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Bulletin of Prosthetics Research

REHABILITATIVE ENGINEERING RESEARCH AND DEVELOPMENT

DEPARTMENT OF MEDICINE AND SURGERY
VETERANS ADMINISTRATION . WASHINGTON, D. C.

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Eugene F. Murphy

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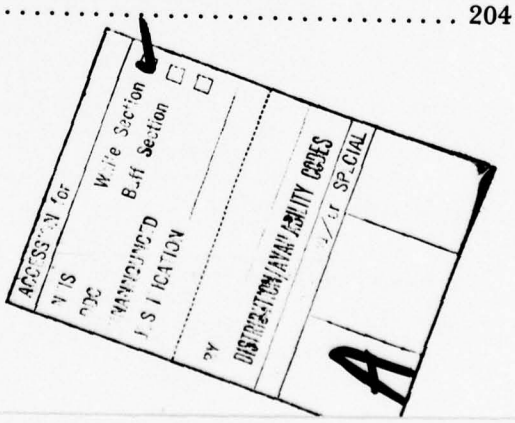
CONTENTS



TECHNOLOGY TRANSFER

Eugene F. Murphy, Ph. D.

Editor
Bulletin of Prosthetics Research

Rehabilitative Engineering Research and Development Service
Office of Technology Transfer
252 Seventh Avenue, New York, N.Y. 10001

. . . an editorial

In recent months there have been a number of changes in form, titles, personalities, and functions in the Rehabilitative Engineering Research and Development Program.

In August 1977, Mr. Earl Lewis, formerly the Editor of the Bulletin of Prosthetics Research and Assistant Director of the Research Center for Prosthetics, was transferred from the research program to the Office of the Assistant Chief Medical Director for Academic Affairs. Mr. Lewis became Director of the Rehabilitation Engineering Education Program, physically located at Wadsworth VA Hospital in Los Angeles but responsible for a nationwide program of education for many disciplines in the various aspects of rehabilitative engineering. In his new post, he continues the same functions regarding the educational program which he had carried out effectively in the Research Center for Prosthetics. These include assignment of VA employees, primarily doctors and therapists, to the organized Prosthetics Education Schools at the University of California, Los Angeles, Northwestern University, Chicago and New York University, New York, as well as organization and conduct of periodic intramural intensive educational programs, and organization of new and special courses to meet VA needs. By agreement with the Driver Education Program in the Rehabilitation Medicine Service under the Assistant Chief Medical Director for Professional Services, he is organizing a major program to train VA driving instructors in the special problems and opportunities offered by the newly emerging types of automotive adaptive equipment, to enable severely handicapped patients to drive cars or vans.

On October 1, 1977, Dr. Vernon L. Nickel, formerly of Rancho Los Amigos Hospital at Los Angeles, became Director of the Rehabilitative Engineering Research and Development Service, under the

Assistant Chief Medical Director for Research and Development, Dr. Thomas F. Newcomb.

Effective April 22, 1978, the Chief Medical Director announced that the Administrator approved the reorganization of the Research Center for Prosthetics as the Office of Technology Transfer, with myself as its Director.

The principal function of the Office of Technology Transfer is to expedite the transfer of research results in Rehabilitative Engineering R&D to clinical practice. This is a somewhat different use of the term "technology transfer" from that in some other agencies, which transfer novel technology from their own field, such as space, to applications in other fields. There *have* been a few examples of transfer of rehabilitative engineering research and development results to other fields. One rather amusing example, many years ago, was the development of a special high-strength but very flexible chain for control of certain artificial arms by the Sierra Engineering Company. While rapid evolution of artificial arms at that period eliminated the need for the chain for its original purposes, we were fascinated to learn that considerable quantities were used in control systems for rockets. It was an early example of "reverse technology transfer" from a mundane application to the aerospace field. That was years before NASA was given the charge of transferring its space-age technology to other applications.

There has, of course, always been an emphasis throughout the Prosthetic and Sensory Aids Research Program upon rapid transfer of research results to widespread clinical practice, not only for veterans but also for others. Public Law 729 of the 80th Congress, passed in June 1948 and later recodified in various forms, not only authorized research in prosthetic and sensory aids by the Veterans Administration but provided that the Administrator might make the results available so that all disabled might benefit. The participants in the program have always interpreted this provision vigorously—it was not enough to deposit a copy of a report in some public library, or make a few prototype models available to a small number of patients. In addition, on a much broader scale, they disseminated research results through publications, scientific papers, exhibits at professional meetings, appropriate motion picture films, and development of early prototypes through successive evaluation models into routine mass production. Continuing education was provided, not only to VA clinicians and VA orthotic laboratory supervisors, but to the private practitioners, therapists, prosthetists, and orthotists who served civilians as well as veterans.

The VA has also always been interested in making its results available to foreign nations, through assisting in the organization

and conduct of international courses, participation in conferences, and special teaching assignments in foreign countries in cooperation with the State Department, WHO, foreign governments and voluntary organizations. VA staff and contractors have traveled extensively, both to impart information and to learn of new developments elsewhere. These have been further applied in this country, or have served as the basis for still further improvements for the benefit of all disabled. This active role in the dissemination of information led to support of a variety of books and journals, including the Bulletin of Prosthetics Research, and to the varied educational programs, now transferred to Academic Affairs.

Any division of functions is bound to be relatively arbitrary, since ultimately the functions are again combined and coordinated under some higher official such as the Chief Medical Director or the Administrator of Veterans Affairs. Thus, the organizational structure, hopefully, is more a reflection of a policy that permits each individual office and participant to exercise his best talents and energies in the fields at which he is most effective. Unfortunately, none of us are omniscient nor omnipotent, able to know all aspects and perform all functions equally well—certainly the task of replacing human parts and functions calls for more knowledge, ability, and energy than any single person can possibly possess. Individual experts must work in coordinated fashion.

The Office of Technology Transfer, in attempting to accelerate transfer of research results to widespread clinical practice, will have a variety of functions. The immediate top priority is to accelerate the publication of this Bulletin of Prosthetics Research, an important function though sometimes increasingly delayed due to regrettable but often uncontrollable circumstances. The Fall 1977 (10-28) issue was due out about the first of July. It is anticipated that this Spring 1978 (10-29) issue will be issued about September 30th. Every effort is being made to issue the Fall 1978 (10-30) issue shortly after Christmas 1978 and to continue to accelerate future issues until the actual issue date is recognizable within the nominal period. This course seems preferable to arbitrarily redating an issue and seeming to miss a semi-annual period.

For some years there have been increasingly formal efforts to provide more intensive review of manuscripts submitted for publication in the Bulletin before acceptance. This has involved increasing use of external reviewers knowledgeable in the field but used on an anonymous basis. It is expected that these informal reviews will continue on an ad hoc basis as necessary, but that an Editorial Advisory Board, representing a broad variety of disciplines in the many fields of interest, will eventually be set up.

The box on the front cover, below the title Bulletin of Prosthetics Research, has tended to show the agency component publishing the magazine. Originally it was Prosthetic and Sensory Aids Service, then Research Center for Prosthetics. With this issue it is being changed to Rehabilitative Engineering Research and Development, indicating both that the Office of Technology Transfer is an agency of the Central Office RER&D Service, the real sponsor, and also, perhaps, serving as a subtitle to the term Bulletin of Prosthetics Research to indicate the broad field covered.

There have been occasional suggestions that the title should be changed from Bulletin of Prosthetics Research to any of a variety of other possible names to indicate something broader than the narrow connotation of prosthetic devices as "artificial limbs" alone. The term prosthesis can of course represent a wide variety of other artificial body parts: for years the Veterans Administration has interpreted the term to cover a wide variety of other devices including orthoses, cosmetic restorations, sensory aids, automotive adaptive equipment, spinal cord injury equipment, etc. Indeed, the General Counsel of the Veterans Administration many years ago ruled that a law permitting the Administrator to provide "prosthetic devices without regard to other provision of law" could be used to cover a very wide range of devices—not just artificial limbs. In this sense, then, "prosthetics" is used as a short title for the science and art of replacing or supplementing any of a variety of missing or defective body parts and functions, rather than listing a long and almost inevitably incomplete catalog of possible devices in various documents including the title of this magazine. Similarly, "research" has been interpreted to include not only basic and applied research but also the much longer process of development, evaluation on an increasingly wide scale, and various efforts toward application of research results to practical use.

One of the functions of the Office of Technology Transfer is to maintain a Reference Collection, originally organized over 25 years ago and containing items still older, including some relatively rare foreign language documents from World War I and earlier, and reports not only of the Veterans Administration but of other agencies. A note describing the Reference Collection is published in the Notes and News section of this issue.

The predecessor office, the Research and Development Division of the Prosthetic and Sensory Aids Service, was active in the preparation of a variety of films and manuals, both for professionals and in some cases for the patients themselves. Many of these are now obsolete and need to be revised. It is anticipated that films will be updated in coordination with the Medical Media Division, Learning

Resources Service, Veterans Administration, Washington, D.C. Some types of manuals directed to patients are anticipated for revision, and ultimate availability both through VA field stations and for sale to the public at the Superintendent of Documents office of the Government Printing Office. Similar information intended for patients will be prepared to cover other types of disabilities which had not been served in the past.

It is anticipated that the Bulletin will continue to provide both scientific and technical papers appealing to a broad interdisciplinary audience interested in a variety of devices, and also a variety of information of VA-related and supplementary kinds, such as news and notes, brief reports on VA research projects, listing of Publications of Interest from current literature, Recent Patents, and a Calendar of Events.

Papers are solicited from both VA and non-VA investigators and clinicians. Long-term readers will remember that the Bulletin has frequently published reports on projects sponsored by other agencies, notably the Rehabilitation Services Administration of the Department of Health, Education, and Welfare with which the VA Rehabilitative Engineering Program is carefully coordinated. There have been articles appealing primarily to any of the variety of disciplines, whether doctors of different medical specialties, engineers of various types, prosthetists or orthotists, therapists, rehabilitation workers, etc. Because the Bulletin's audience is interdisciplinary (and because many of the major articles in-and-of-themselves are interdisciplinary) we have felt a special obligation to present even the most highly technical material with the clarity and precision needed to make it accessible to any intelligent reader—whether or not he or she happens to be another specialist in the particular discipline, area, or device being discussed.

We intend to try to improve our approach to this difficult style of editing, working closely with our authors and reviewers. The goal will be to organize, within the presentation of a paper, that relatively informal and basic description of the material needed by readers trained in disciplines other than the authors'. With this concept established early in the paper, it should be possible to introduce more highly technical nomenclature where it is needed to achieve precision in concept. Mathematical derivations, if needed, may be supplied as appendices. Obviously, providing to each reader real accessibility to new knowledge without loss of detail in reasoning or fact is not easy. However, in a field so interdisciplinary as this, it seems surely necessary.

The Bulletin has often printed articles of a considerable length without imposing the tight space limitations appropriate to spe-

cialized journals, which can assume a great deal of knowledge on the part of their readers within a highly specialized field. There has also been generous use of illustrations in order to make the material moderately intelligible even at a glance and, incidentally, in order that the illustrations and their captions might help to serve as dictionary or glossary for any term which may not be familiar to the reader.

We have been grateful for our foreign readers and have tried to be aware of the special need for clarity of material by those whose native language is not American English. It has also been apparent that the same word is often used with different connotations either in different fields or in separate countries: thus, "fatigue" has quite a different meaning in physiology and in the engineering study of strength of materials. Similarly "stress" has a different meaning to physiologists or psychologists than to civil and mechanical engineers. There are names for parts or terms in prosthetics and orthotics which have been used differently in the United States and in the British Isles. To a non-English-speaking reader, attempting to translate a difficult word with the aid of a dictionary may well cause confusion. In editing an attempt is made, not always of course successfully, to help avoid a misunderstanding.

The Bulletin is fortunate in having gained, early in its publication, recognition by the Engineering Index and then by the Index Medicus. It is also being indexed in the Rehabilitation section of Excerpta Medica. Thus we hope major articles come to the attention of specialists in a variety of disciplines and countries. It is hoped that further vigorous efforts to accelerate and further improve the Bulletin will continue to justify such widespread indexing and abstracting.

There is sometimes an unfortunate tendency for researchers to believe that, in a rapidly changing field, nothing older than 5 years or so is worth searching. The tendency to use online computer searches such as Medline (Medical Literature Analysis and Retrieval System On-Line) perhaps accelerates such a trend. Unfortunately, such a limitation may well lead to unwitting duplication of past efforts, or to overlooking obvious possibilities for revival of old-but-good ideas which somehow were not successfully reduced to practice when first proposed.

One famous example is the suction socket, patented by Dubois D. Parmelee of New York City in 1863. There were a number of later attempts at the same basic idea, as shown by the patent literature. Finally there was an extensive trial, started immediately after World War I in England, but abandoned because some 26 of 28 users had rejected the socket. Years later, however, two were

still successfully wearing theirs. Presumably, this was because their stumps had retained essentially the same shape, so of course their sockets continued to fit. The suction socket concept was revived at two places in Germany in the 1930's and independently on a very small scale by a limb maker in New York City, who apparently fitted only a few cases. Use in some, but not all, parts of Germany expanded rapidly during World War II.

The suction socket technique was brought back to this country as a proposal for evaluation by a commission sent to Europe by the Surgeon General of the United States Army, in March 1946. After extensive trials coordinated by the National Research Council's Committee on Artificial Limbs, the suction socket concept was recommended to the Veterans Administration as a worthwhile form of fitting provided that each was prescribed by a qualified surgeon and fitted by a specially trained limb fitter. The Chief Medical Director of the Veterans Administration, in October 1947, then asked the National Research Council to arrange for such specialized training for both surgeons and limb makers. This training, pioneering rehabilitative engineering education, led not only to specialized continuing-education schools but to certification of the qualified limb makers. That was an important step toward the upgrading of limb makers into the more professionally oriented prosthetics profession of today. From the introduction in the Spring of 1946, there were intensive and coordinated efforts. There was a vigorous program by the Spring of 1948, and soon afterward an increasingly widespread chain of clinic teams composed of physicians, therapists, prosthetists, and prosthetic representatives to follow up not only the rapidly increasing number of suction socket cases but other types of patients as well.

The whole concept of the Orthopedic and Prosthetic Appliance Clinic Team in the Veterans Administration had been tried first at San Francisco and then in New York in 1949 and was widespread throughout the country by the 1950's. Some years later a National Research Council survey indicated at least 400 clinic teams, mostly in private medical centers and other institutions, throughout North America. The concept of the clinic team was, in turn, widely taught at international prosthetics courses beginning in 1957, leading to worldwide acceptance of the concept.

Lessons from this and many other examples of attempts at transfer of research results through evaluation into wider dissemination will be used in the entire Rehabilitative Engineering R&D Program, with the Office of Technology Transfer as a key element in promoting expeditious transfer. It is anticipated that this Bulletin will be an increasingly effective tool in such efforts.

CLINICAL EVALUATION OF A SENSORY FEEDBACK DEVICE: THE LIMB LOAD MONITOR[a]

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I. INTRODUCTION

Ambulation training is an important phase of the rehabilitation process for patients with any of a variety of pathological conditions. The ability to shift laterally in order to achieve single-limb balance is essential for functional gait, but may be impaired in patients with brain damage, lower-limb amputation, or hip joint replacements (1). In addition, a specific amount of weight-bearing on one limb is often prescribed for patients with various orthopedic conditions such as malunion fracture or pinned hip fracture. Therefore, the final ambulatory goal is often divided into such subgroups as standing balance, weight-shifting ability, and achievement of adequate limb loading. Various patients, however, are unable to achieve all of these sub-goals. For example, the patient who has just received a lower-limb prosthesis may be afraid to load the artificial limb fully. Patients with sensorimotor disabilities may lack the sensory information or sensory processing ability necessary to develop these standing skills and are, therefore, unable to achieve an optimal walking performance.

[a] This report was prepared as part of the work under Grant No. 23-P-55518 from the Rehabilitation Services Administration, Department of Health, Education, and Welfare, Washington, D.C.

In the usual clinical environment, the clinician has very few methods by which to help the patient appreciate appropriate limb loading. Two commonly used tools are bathroom scales and full-length mirrors (2). The use of the bathroom scale requires that the patient load the affected limb to the desired amount and then remember this load during walking. However, neither clinician nor patient is sure that the loading which occurs during walking matches the loading that occurred during standing on the bathroom scale (3). The use of the mirror serves to remind the patient to stand or walk "straight" and not to lean toward the sound limb and away from the affected limb. However, an erect posture does not necessarily correlate with symmetrical loading (4). Therefore, both of these methods are less than optimal in helping the patient to achieve proper loading.

In instances where enhanced sensory input may lead to development of controlled motor activity, augmented sensory feedback has been used. By use of adequate instrumentation, feedback equipment can give information through alternate sensory channels (e.g., auditory, visual) about the rate and amplitude of movement; augmented feedback is immediate and contingent upon the success, or lack of success, in achieving performance (5).

The Limb Load Monitor is a clinical tool used to enhance relearning of posture and locomotor skills of patients. Based on the rationale of augmented sensory feedback, this device is designed to provide a proportional auditory signal which correlates with the amount of weight placed on a limb. The auditory tone provides an error signal if actual loading does not match the intended loading. Therefore, the alert and oriented patient has accurate additional feedback information which may allow correction of aberrant performance. In addition, the clinician is provided with an objective measurement of the patient's progress in achieving the loading goal.

BACKGROUND INFORMATION

The Limb Load Monitor (LLM) was developed at the Krusen Center for Research and Engineering, Moss Rehabilitation Hospital, to enhance the ambulation treatment program. It was specifically designed to aid in the achievement of proper limb loading critical for optimal walking performance. In order to replace or augment such methods as bathroom scales and mirrors, the LLM had to be dependable, clinically useful, and practical enough to justify cost.

The Krusen Center staff focused on two major objectives during the development of the LLM: (i) to design a reliable electronics package and (ii) to document the clinical utility of the device.

Description of the Device

The LLM consists of a pressure transducer connected by wire to a small control box (Fig. 1). The transducer is built into a shoe insole and is meant to be worn inside the shoe. The control box, which weighs 9 oz, is meant to be worn attached to the patient's belt. The control box contains the source for an auditory signal which varies in frequency in proportion to the pressure being exerted on the transducer.

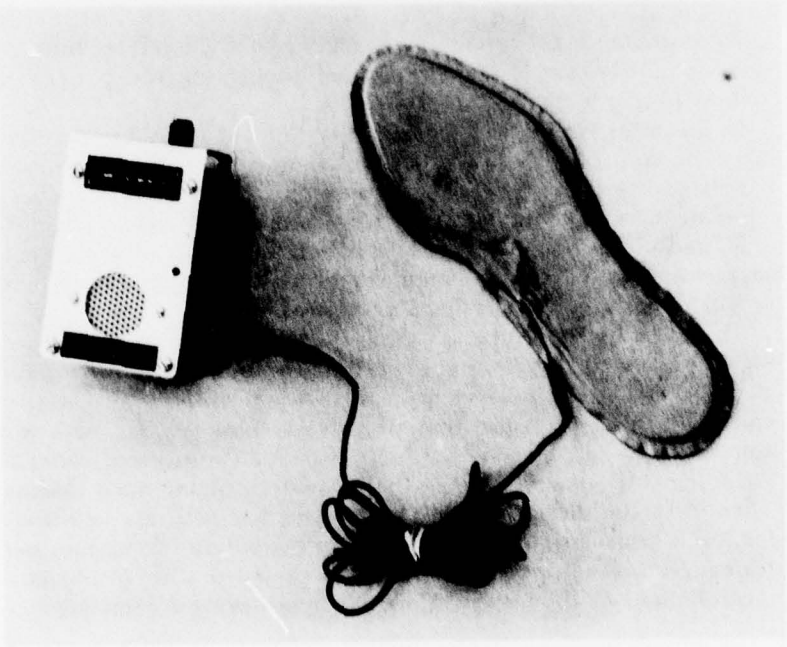

FIGURE 1. The Limb Load Monitor (LLM) consists of a pressure sensitive shoe insole, connected by wire to a box containing controls and a sound generating device. The box is intended to be worn on the patient's belt.

The LLM provides two treatment mode possibilities: in "Mode 2" the sound decreases in frequency with increased loading and becomes silent when the loading goal is reached; in "Mode 3" the sound begins at the calibrated loading level and increases in frequency with increased weight bearing.

The controls include a switch for selecting one of the two treatment mode possibilities, and a control knob for adjusting the sound

"null" point which indicates to the patient that the desired loading has been reached. To calibrate the LLM, the patient loads the limb on a bathroom scale while the null point setting is adjusted. There is also a control for sound volume. The side of the control box provides a jack to accept the input from the transducer and another labeled "earphone." Insertion of an earphone plug automatically diverts the signal to the earphone and silences the small "loudspeaker" type sound generator in the control box.

Previous Clinical Testing "In-House" and Outside

With the clinician in mind, the Krusen Center felt it a responsibility to demonstrate not only the validity but the clinical efficacy of the LLM. Bench and laboratory testing at the Krusen Center during the past 5 years has shown that the final prototype accurately and reliably measures the vertical limb loading (6). In addition, Wannstedt and Herman conducted a clinical study on patients with hemiplegia (classified as stable) in their recovery of function (7). Findings of this study indicated that patients were able to use the LLM to learn to stand symmetrically and then were able to retain this skill in the absence of the feedback device. In this "in-house" study, the equipment was operated by trained personnel and engineering expertise was immediately available, so equipment failure was not a factor in the results which suggested that it was clinically feasible to incorporate the LLM into the treatment program of patients with locomotor dysfunction.

The next stage of testing naturally involved clinical use by staff physical therapists outside of the Krusen Center. Several clinical trials were conducted at various hospitals: three in Philadelphia, and one each in Massachusetts, New Jersey, and Kentucky.

Those tests were conducted to determine clinical acceptability, equipment reliability, and usefulness of the LLM to the patient and to the clinician. Results indicated that the clinician could learn to operate the device and that, when appropriately selected, patients with either neurologic or orthopedic disability (or both) were able to understand the purpose of the auditory signal. In addition, the prototype of an improved LLM was fabricated in response to the therapists' suggestions. Finally, as a result of those trials, an operating and treatment manual was developed with the purpose of transferring operating and equipment maintenance information to the clinician who would purchase the LLM (8,9).

The studies completed at the Krusen Center and within the various hospitals suggested that the LLM was a reliable device and that careful instruction on its use would enhance its clinical success. The results also indicated that the LLM could enhance postural con-

trol and loading awareness in patients. Therefore, the necessary next step was to conduct an extensive, more highly organized, trial to document the effect of the device on patient performance, the actual utilization of the device, and a practical method for introducing the device to the clinician.

FIELD TRIAL DETAILS

Purposes

The purpose of this field trial was to document: (i) transfer of information from the laboratory to the clinical setting; (ii) utilization of the LLM among patients with similar functional diagnoses; (iii) effectiveness of the LLM in attaining treatment goals; and (iv) reliability of the LLM in the clinical setting.

Outline of Procedure

The plan developed to fulfill the stated purpose can be outlined as follows:

1. identification of facilities interested in a cooperative investigation;
2. selection of a liaison with each facility;
3. training selected staff members in device operation;
4. having patients selected to use the device in treatment;
5. record keeping of initial and final status, outlined treatment goal, and patient's daily progress with the device;
6. evaluation of the clinical utility of the device.

This plan was instituted using the procedure to be described.

Participants

The formal trial period was planned to extend from September 1976 to June 1977. Five centers agreed to participate in the trial. Participating centers and personnel were as follows:

1. **Ontario Crippled Childrens' Centre, Toronto, Canada**
   Physical Therapy Department
   Elaine Sharp, M.H.Sc., Coordinator
   [b] Linda Ross, P.T. (Attended Moss Workshop)
   [b] Marissa Marshal, P.T.
2. **Rehabilitation Engineering Center, Harvard-M.I.T., Boston Childrens' Hospital Medical Center, Boston, Massachusetts**
   Physical Therapy Department
   [b] Janet Cox, L.P.T., Coordinator (Attended Moss Workshop)
   Claire F. McCarthy, L.P.T. Director of P.T.

[b] Staff members primarily responsible for clinical use of the LLM.

[b] Dana McLaughlin, L.P.T.
[b] Lynne Wiesel, L.P.T.

3. **Rehabilitation Engineering Center, Northwestern University, Chicago, Illinois**
   Mayola Cotterman, L.P.T., Coordinator (attended Moss Workshop)
   A. **Cook County Hospital**
      Physical Therapy Department
      Louise Nelson, Director of P.T.
      [b] Arlin Duboer, L.P.T.
   B. **Mercy Hospital**
      Rehabilitation Department
      [b] Maureen Birk, L.P.T., Director of P.T.
   C. **Rehabilitation Institute of Chicago**
      Physical Therapy Department
      Patricia Kammerer, L.P.T., Director of P.T.
      [b] David Duff, L.P.T.
   D. **University of Illinois Hospital**
      Department of PM&R/Physical Therapy
      June Schroeder, Director of P.T.
      [b] Kathy Manella, L.P.T.
      [b] Janice Hubatch, L.P.T.
4. **Rehabilitation Engineering Center, Rancho Los Amigos Hospital, Downey, California**
   Michael Quigley, C.P.O., Coordinator
   A. **Amputee-Fracture Service, Physical Therapy Department**
      [b] Norma Mills, L.P.T., Director of P.T.
      [b] Antje Hunt, L.P.T.
   B. **Long Beach Memorial Hospital**
      Department of Physical Therapy
      Norma Shanbour, L.P.T., Director of P.T.
      [b] Gail Teaford, L.P.T.
   C. **Physical Therapy Graduate Student Project (12)**
      [b] Melinda Allen
      [b] Joyce Landes
      [b] Stephanie Talley
5. **Woodrow Wilson Rehabilitation Center, Fishersville, Virginia**
   Physical Therapy Department
   Patty Altland, M.S., Director of P.T.
   [b] David Dery, L.P.T. (Attended Moss Workshop)

A coordinator was selected at each of the five sites to supervise the clinical trial within the original site or to identify other hos-

[b] Staff members primarily responsible for clinical use of the LLM.

pitals in the area where physical therapy departments would be suitable for clinical testing. In this latter instance, the coordinator would serve as a liaison between Krusen and the additionally selected hospitals, as well as with the original site.

Transfer of Information to Participants

On September 20-21, 1976, a two-day workshop was held at the Krusen Center for the coordinators and other representatives from the participating centers. The course was designed to transfer information about the purpose of the field trial and method of operation of the LLM.

Local Site Selection

Upon return to their facilities, each coordinator selected appropriate local testing sites—10 facilities were involved in this process. The coordinators at OCCC, WWRC, and Harvard-M.I.T. supervised the trial within their own institutions, while those at NU and RLAH selected additional sites.

The originally selected sites at Northwestern University included the physical therapy departments at the University of Illinois Hospital, Cook County Hospital and Mercy Hospital. Five months later, the Rehabilitation Institute of Chicago was added at its own request and the rehabilitation department at Mercy Hospital was selected to replace the general department.

Originally, the amputee and fracture service was the trial site for RLAH. At the 6-month site visit, San Pedro Peninsula Hospital joined the test facilities. Long Beach Memorial Hospital began to participate in the 8th month of the trial.

Table 1 lists the type of facility and patient population served at each site. (Of the 10 sites selected, information from 9 was found appropriate.)

LLM Distribution and Maintenance: Each of the five coordinators was given three LLM and 20 insoles of various sizes. They were instructed to request additional units if needed, and to return any equipment that did not work.

Materials Provided: Treatment manuals were provided for each LLM, and a sufficient number of forms for progress documentation was given to each facility (Table 1; Appendix A:1-2).

Communications with Participants: In addition to an initial evaluation and daily treatment evaluation, opinions of the clinical staff about the LLM were to be collected in two ways: formally, through

TABLE 1—*Sizes and Types of Participating Trial Sites*

Hospital	Facility	Patient population	Target patients/month	
			Amputees	Hemiplegias
OCCC	1. Teen Unit, P.T. Dept. 2. Prosthetics Unit, P.T. Dept.	1. Children; outPatient 2. All kinds of amputa.	– 2	4 –
Harvard-MIT	1. OutPatient Developmental Disability Clinic 2. InPatient Ortho-Neuro Clinic	1. Children; CP, very few hemiplegias 2. Children orthop.; amp. and neurology	– <1	n/a –
Cook County Hospital	Acute-care P.T. Department	Varied general-hospital clientele; long-term patients referred to rehabilitation facilities	2	–
Mercy Hospital	Rehabilitation specialty: long-term	All types of handicaps	(5)	6
RIC	Rehabilitation specialty: long-term	All types of handicaps	(41)	79
University of Illinois Hospital	Acute-care P.T. Department	Varied general-hospital clientele; long-term patients referred to rehabilitation facilities	4	(4)
Rancho Los Amigos Hospital	Amputee–Fracture service	All kinds of amputations for L.E., mostly "Syme's"	(60-90) 12-18	–
L.B.M.H.	Neurology and Rehabilitation	Neurological handicaps	–	10
W.W.R.C.	Vocational Rehabilitation	All kinds of long-term handicaps	5	3

Note: Figures in parentheses are approximate.

a questionnaire to be completed by the therapists at the end of the trial and, informally, at each site visit, through interviews at staff meetings. Visits to each of the clinical sites were made in October 1976, and in February-March and July, 1977. (Northwestern University was visited on one other occasion, in May 1977.) Regular contacts were made with the participants between visits via telephone calls and letters, and contact was established whenever any questions or problems arose at any of the centers.

Patient Selection Criteria and Therapy Goals

Two target groups had been identified for LLM training; patients with lower-limb amputation, and patients with hemiplegia. Each site was assigned a specific target group or groups.

In order to be a LLM candidate, the patient was to be either a patient with hemiplegia or a patient with a lower-limb amputation. In addition, the patient was to have a limb-loading problem and to fulfill the selection criteria outlined in the pre-evaluation form (Appendix A:1). If the patient was an appropriate candidate, the purpose of training with the LLM was to be able to achieve controlled weight-bearing on a limb. Specific goals for therapy were either (i) to prevent excessive loading, (ii) to maintain a load level, or (iii) to increase actual weight-bearing on the limb. The specific goal selected, and the daily progress made in achieving the goal, were to be recorded on the evaluation and progress note forms (Appendix A:2).

The training of controlled loading could be achieved either during quiet standing, or in shifting weight from side-to-side, or during walking. Therapists were asked to record the manner which they selected to approach this goal. They were also asked to record the mode of auditory signal used; i.e., either "2" where the sound decreases in frequency with increased loading, or "3" where the sound increases in frequency with increased loading beyond a calibrated threshold.

FIELD TRIAL RESULTS

Of a total of 75 participant months (determined by adding the number of months that each facility participated in the trial) 56 months were spent in actual testing of the LLM (Fig. 2).

Six additional LLM's were requested and distributed during the clinical trial. Only four LLM's used during this trial were reported to malfunction; these devices were either repaired by the Krusen staff or repaired locally. The insoles performed without problem

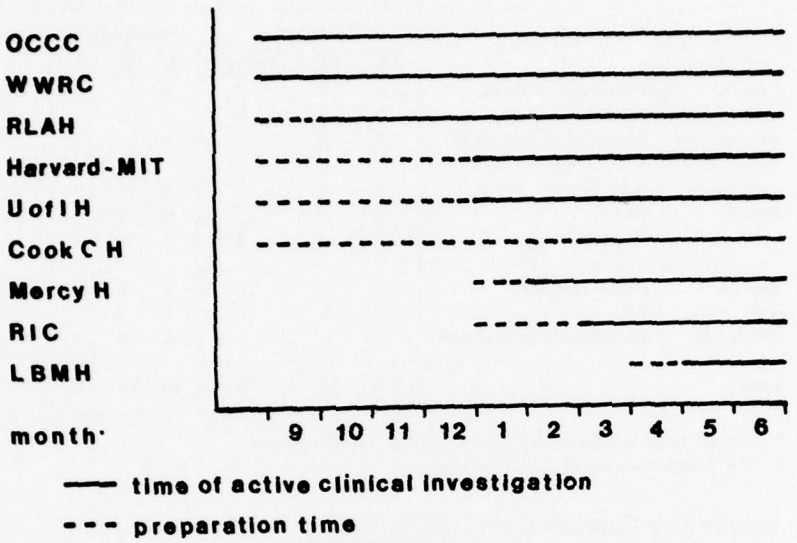

FIGURE 2.—Actual time period of involvement in study by the various centers.

and the insole breakdowns that occurred were the result of intensive use. (In one clinic, three insoles were worn so thin that they no longer worked accurately and had to be replaced. Where this occurred, the insoles had been taped to the outside of the shoe of the prosthetic foot because the shoe was too tight to allow room for the insole. Repetitive use in this fashion tended to wear out the transducers prematurely.)

Relative Utilization of the LLM in the Clinical Setting

Patient Sample

A total of 81 patients were selected; 44 were patients with lower-limb amputation and 37 were patients with hemiplegia. Table 2 shows the number of patients seen at each center.

The age range of the patients was 7-83 years, with a mean of 46.3 years. The clinics could be divided into three subgroups with regard to age: the two children's hospitals saw patients with a mean age of 14.6 years, the six rehabilitation or general departments for adults had a mean age of 59.2, and the vocational rehabilitation center served clients with an average age of 38.9 years. The mean ages for the hemiplegic and the amputee subgroups were the same as the corresponding age group in the overall sample.

TABLE 2.—*Number of patients of each target group type who used the Limb Load Monitor.*

Target group	Name of center	Amputation			Hemiplegia			Total
		AK	BK	Other[a]	L	R	?	
Patients with Amputation	University of Ill. H.	5	0	4	3	—	—	12
	Cook County H.	2	5	0	—	—	—	7
	Rancho Los Amigos H.	5	3	1	—	—	—	9
Mixed	W.W.R.C.	2	4	2	4	4	—	16
	OCCC	2	2	0	4	2	—	10
	Harvard-M.I.T.	1	0	2	1	0	—	4
Patients with Hemiplegia	Mercy Hospital	—	—	1	1	1	3	6
	RIC	—	3	—	6	5	1	15
	Long Beach Memorial H.	—	—	—	1	1	—	2
Total	9	17	17	10	20	13	4	81

[a] "Other" include bilateral amputees and hip disarticulations
? = No information about side of lesion

Sample Size Compared with Target Group Population

The overall average percentage of the amputee population selected to use the LLM was 27 percent (7-41 percent), while the average percentage of the hemiplegic population selected was 21 percent (17-27 percent). These figures were computed by comparing the number of target group patients selected to the total number of target group patients seen by each facility per month. Figure

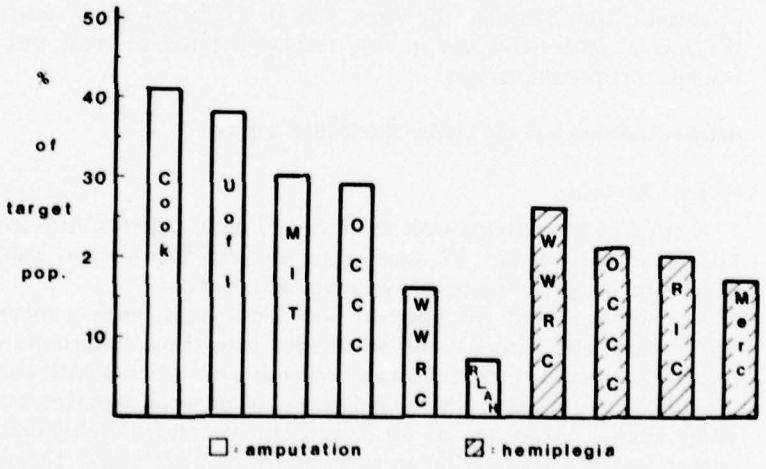

FIGURE 3.—Number of patients using LLM seen during the trial, expressed as percentages of the total target groups. (LBMH not included because of its short participation time.)

3 reveals the wide range of relative utilization in the various facilities.

LLM Usage Per Therapist

An estimate of the average number of patients using the LLM seen per therapist can be made, when the number of actively participating therapists is considered together with the number of patient forms submitted during the trial period. The number of patients selected per therapist per month was between 0.2 and 0.4 in both patient groups. This estimate is shown in Table 3 where it may be seen that, if only the target population is considered, the trial activity level remains fairly consistent among the various clinics.

TABLE 3—*LLM usage in terms of number of patients/therapists/month. The figures refer only to target groups, not total patient sample.*

	No. of therapists	No. of months	Patients with amputation	Patients with hemiplegia
Univ. of Illinois H.	5	6	0.3	–
Cook County H.	6	4	0.3	–
Rancho Los Amigos H.	3	9	0.3	–
W.W.R.C.	5	10	0.2	0.2
OCCC	2	10	0.3	0.3
Harvard-M.I.T.	2	6	–	0.3
Mercy Hospital	4	5	–	0.3
RIC	8	4	–	0.4
Long Beach Memorial H.	1	2	–	1.0
Mean ($\bar{X}$)	4	6.2	0.3	0.4

Number and Duration of Treatment Sessions with the LLM

The number of treatment sessions in which each patient used the LLM varied greatly among centers as well as among patient groups. The total number of sessions was 467, with an average of 6 treatments per patient. The hemiplegic patients used the LLM from 1 to 22 times each, with an average of 4 times, while the amputees used the device during 1 to 54 sessions with an average of 7 treatments per patient. Figure 4 shows the distribution of treatment activity among participating departments.

The actual duration per session in which the LLM was in use did not vary greatly (20-60 minutes) and only occasionally was a patient reported to use the device during a whole day.

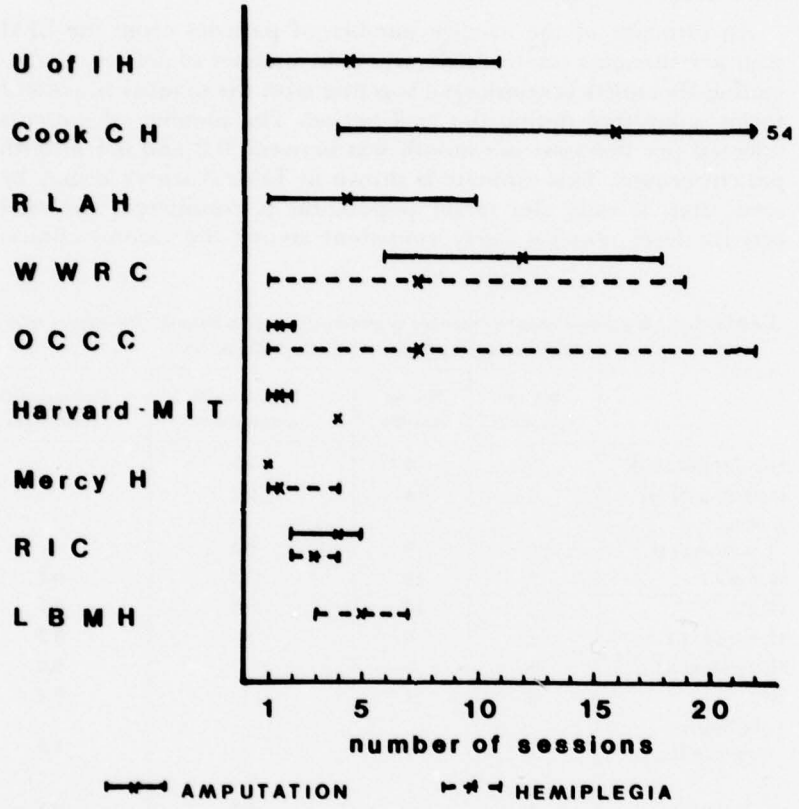

FIGURE 4.—Average and range of number of treatment sessions/patient at the various centers.

Estimated Utilization

The frequency of LLM use during this field trial was related to the number of therapists active at a center and to the type of patient population at the center. In Table 4, the reported trial activity can be seen as a function of "active" therapists and "active" time span. In a department geared towards total care of the patient with lower-limb amputation(U. of I., Cook County, WWRC, RLAH, see Table 1), the therapist applied the device an average of 2.7 times

per month. If, on the other hand, the therapist treated acute hemiplegic patients, or amputees with additional medical problems (Mercy, RIC, see Table 1), the actual number of sessions was less (average 0.9 sessions/therapist/month) but the same number of patients used the LLM (refer to Table 3).

TABLE 4—*Average LLM utilization per month during the trial. Target group for each facility is underlined.*

Clinical Site	Amp.	Hemi.	Monthly Utilization
U. of I. H.	1.4	0.2	1.6
Cook County H.	4.7	–	4.7
RLAH	1.4	–	1.4
WWRC	1.9	1.2	3.1
OCCC	0.3	2.3	2.6
Harvard – MIT	0.3	0.3	0.7
Mercy Hospital	0.1	0.4	0.5
RIC	0.4	0.8	1.2
LBMH	–	5.0	5.0
$\bar{X}$ of all sites	1.2	1.1	2.3
$\bar{X}$ of target	1.7	1.7	–

Two of the participating clinics were in children's hospitals (OCCC, Harvard). At these particular physical therapy departments, the patients with amputation were seen as out-patients for fittings and checks only, and the LLM was used only once or twice; the occasional hemiplegic patients with loading problems sometimes stayed in the hospital and were treated for varying lengths of time in the children's centers (Fig. 4 and Table 4).

Effectiveness of the LLM in Attaining Treatment Goals

Treatment Approaches

Among the amputees, the LLM was utilized during walking in 73 percent of the cases (instead of in quiet standing or weight-shifting). The LLM was not utilized at a specific point in gait training by all therapists; instead, its use varied among therapists. For example, some therapists elected to use the device to control loading with an immediate-post-surgical fitting while other therapists used the device for attainment of normal weight-shifting or loading

during walking with the definitive prosthesis.

Thirty-five percent of the hemiplegic patients started use of the LLM in walking.

Fifteen percent of all the patients used the LLM throughout the ambulation training, i.e., for standing and weight-shifting, followed by walking.

The preferred treatment mode was "3" where the frequency of the signal increases with increasing load—78 percent of the amputees and 71 percent of the hemiplegics used this mode in treatment. The other patients used mode "2", in which frequency decreases with increased loading (Fig. 5).

Results of Treatment:

Of the 81 patient records collected, 4 percent (3 patients) of the patient records were not complete. Of the remaining sample, 79 percent (62 patients) were judged to improve with the LLM while 21 percent (16 patients) did not improve. Criteria used to determine improvement were based primarily on the therapist's comments about the ability of the patient to achieve controlled or improved loading or to learn the task of weight-shifting. The therapist's comments were also checked against a comparison of the treatment goal with the recorded progress notes. (Appendix A)

Reasons for lack of success include: (i) equipment malfunction; (ii) lack of patient cooperation; (iii) inability of the patient to understand the meaning of the auditory signal. (This last reason suggests that patients were not selected according to the outlined criteria—review of the progress notes suggests that 8 percent (6 patients) of the sample were improperly selected.)

Among the 79 percent of patients whose treatment with LLM were judged successful, the records from 19 percent (15 patients) indicated that the goal was achieved, but caused genu recurvatum or pain, or there was a lack of "carryover" of the loading in the absence of the LLM.

A separation of the results by target groups yields some interesting findings. The patients with lower-limb amputation achieved the goals in 84 percent of the cases, with 11 percent of these reported to demonstrate inconsistent carryover. Of the patients with hemiplegia, 68 percent responded well to the weight-bearing training, but 27 percent (10 patients) of the group exhibited faulty posture or no carryover from training (Fig. 6).

Closer examination of sub-categories within each of the two target populations showed that the statistics found for the entire group could also be applied at this level: of the 17 above-knee

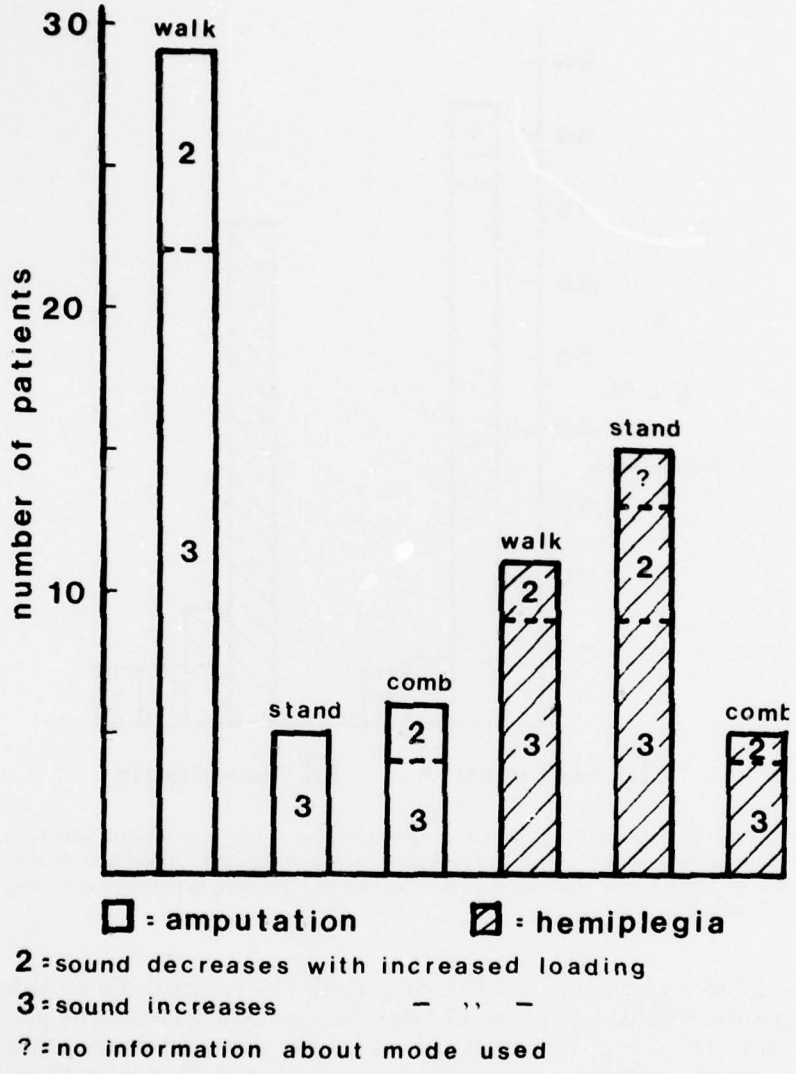

FIGURE 5.—Types of treatment approaches and modes used. (The abbreviated labels have the following meanings: stand = standing balance training; comb = combination of postural and locomotion goals; walk = gait training. 2 = Mode 2 in which frequency of the sound decreases with increased load; 3 = Mode 3 in which the frequency of the sound increases with increased load.)

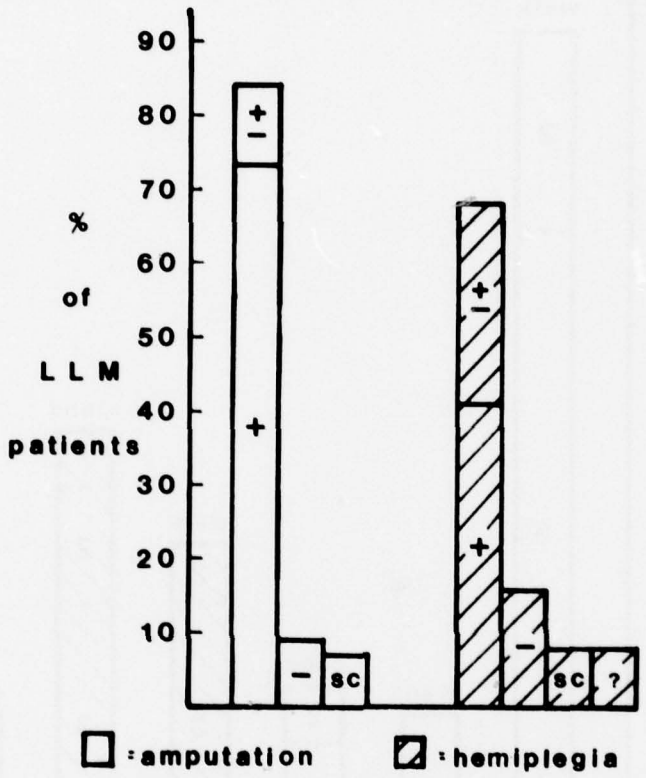

FIGURE 6.—Relative achievement of treatment goals according to the criteria outlined in the text. (Meanings of symbols are as follows: + = treatment goal; ± = not entirely successful; − = did not reach treatment goal; s.c. = not selected according to criteria; and ? = lost, no information about results.)

amputees who used the LLM, 82 percent (14 patients) did so with positive results, and of the 17 below-knee amputees chosen, 88 percent (15 patients) reached the treatment goals; 10 patients had bilateral amputations or hip disarticulations, and 70 percent (7 patients) of these responded well to the treatment.

In the hemiplegic group, 73 percent (16 of 22 patients) of patients with left hemiplegia and 67 percent (8 of 12 patients) of patients with right hemiplegia showed positive results. (The records from three hemiplegic patients did not indicate treatment results.)

Clinicians' Comments on Transfer of Information, Utilization, and Effectiveness

The questionnaires contained 25 questions. A summary of the responses (and the actual questions) is displayed in Appendix B. Some questions were not answered by all therapists; therefore, the results are expressed as the percentage of the response to each individual question.

Questionnaire Responses

A total number of 36 questionnaires were received from 9 centers. (For the number of involved therapists at each center refer to Table 3.) No forms were received from San Pedro Peninsula Hospital.

1. *Transfer of Information from Laboratory to Clinic* (questions 1, 2, 3). The instruction and treatment manual for the LLM was read by 61 percent of the clinicians; 43 percent of the respondents felt that the contents were clear, easily understood, and provided adequate material to allow for operation of the device; 61 percent of the therapists were taught how to operate the device by another clinician, and 25 percent taught themselves; 14 percent had participated in the workshop at Krusen Center.
2. *Ease of Operation and Device Reliability* (questions 9, 10, 11, and 13). Eighty-six percent of the therapists stated that it took less than 10 minutes to calibrate the LLM when they were first becoming familiar with the device (28 percent of these clinicians required less than 5 minutes to set the device). After some practice with the procedure, 81 percent of the sample reported being able to calibrate the device to the desired load in less than 5 minutes.

   Thirty-nine percent of the therapists found that, after the calibration was set to the desired weight, the setting remained stable throughout the treatment time; another 39 percent reported that the calibration changed during treatment, and 22 percent stated that the patient had changed the calibration or that they never checked the setting.

   When asked specifically about the ease of operation, 48 percent felt that the device was easy to operate, 46 percent thought it should be easier to manage, and 6 percent felt it was difficult to use adequately.

3. *Clinical Utility of the LLM* (questions 6, 15, 16, 17, 18, 21). Fifty-three percent of the clinicians stated that their patients always fulfilled the selection criteria, while 47 percent reported that some of the patients would not initially correlate the tone with performance. However, once the patients were selected, 59 percent of the therapists found that the patients were able to load the limb adequately most of the time (22 percent of the clinicians stated the patients were able, consistently, to load the limb to the calibrated level all of the time).

   Most therapists (91 percent) reported that the patients appropriately responded to the LLM during the first or second session. The remaining 9 percent stated that the patients were able to use the device properly by the third treatment session.

   A variety of treatment frequency schedules were employed. For example, 43 percent reported that the patients used the LLM about 3 times a week and 46 percent reported that the LLM was used in daily treatment. Eleven percent used the LLM once a week or one time only. Although 81 percent of the sample used the device only in the clinic, others had the patients utilize the device on the ward or at home. Besides the therapists, those who learned to operate the LLM also included physical therapy aides, students, and patients themselves or their family members.

   In evaluating for clinical utility, an important consideration is the patient's acceptance of the device. Sixty-one percent of the clinicians reported that most of the patients accepted the LLM as part of the treatment program, and 30 percent stated that all of the selected patients accepted the LLM.

4. *Applicability of the LLM* (questions 19, 20, 22). Although the therapists participating in this field study had been asked to record use of the LLM with certain specific patient categories, they had also been told to feel free to use the device on any other patient who seemed likely to benefit from this kind of patient approach. Of the patients selected to use the LLM, the patients with lower-limb amputation were most likely to be selected to use the device (50 percent) followed by patients with hemiplegia (39 percent) and the "other" category (11 percent) which included mostly

orthopedic patients.

When asked if they used the device with more than one category of patients, 21 therapists (58 percent) answered that the question was not applicable to them. Of those therapists who considered it applicable, the majority (66 percent) stated that it was most useful for the amputee category while 27 percent felt that the device was useful for a variety of patients.

When asked to estimate the percentage of the total patient population considered to be LLM candidates, the clinicians' responses were as follows: 38 percent felt that it was applicable to less than 10 percent of the population, 34 percent felt that it was applicable to 10-25 percent of the patient population, 12 percent felt that the LLM could be applied to 25-50 percent, and 16 percent of the sample felt the device would be applicable for more than half of the patient population.

5. *Device Maintenance and Suggested Changes* (questions 7, 8, 12, 23, 24). The majority of the clinicians reported that a working control box (69 percent) and an appropriate insole (56 percent) were available when needed for a patient.

   When asked to comment specifically on any technical changes that would enhance the LLM, 11 percent of the sample were completely satisfied with the device. The remaining people suggested changes in the following factors:

   Auditory signal (28 percent);
   Insole cable (11 percent);
   Weight of the unit (17 percent);
   Size of the control box (13 percent);
   Position and/or shape of the box (13 percent); and
   Texture of the box (6 percent).

   Fifty-one percent of the clinicians would suggest purchasing the LLM for use in a physical therapy department; 23 percent would purchase the device depending on the patient load or if certain changes were implemented (Fig. 7) and 23 percent would probably not recommend purchasing the LLM. (This last group did not comment any further regarding why they would not purchase the device.)

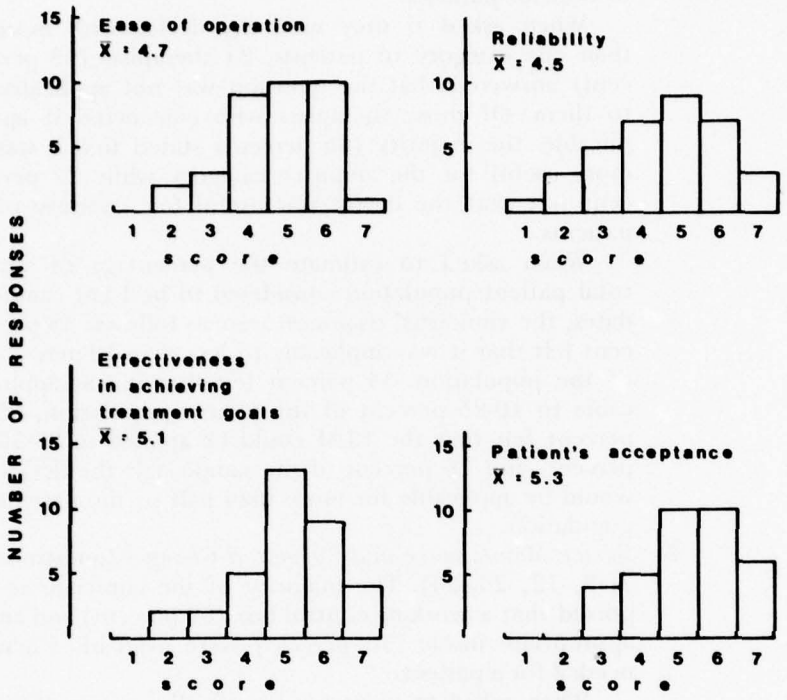

FIGURE 7.—Number of responses to the questions regarding ease of operation, reliability, use of device in achieving treatment goals, and patient acceptance. The therapists were asked to use a scale from 1 to 7, with 7 being the highest score.

In the last question, the clinicians were asked to rate ease of operation, reliability, use of device in achieving treatment goals and patient acceptance on a scale from 1-7, 7 being the highest score.

Ease of operation was rated with a mean score of 4.7 (Modes = 5, 6).

Reliability received a mean score of 4.5 (Mode = 5).

Utility of the LLM as an aid to treatment goals was ranked with a mean score of 5.1 (Mode = 5); and

Patient acceptance received a mean score of 5.3 (Modes = 5, 6)

See Figure 7.

Informal Comments on Questionnaires

Comments were offered on all questions. The most frequently appearing comments included the following:

1. *Comments about Ease of Operation and Reliability:* 23 comments in this area were made in relation to various questions. The largest group of comments (48 percent) dealt with instability and fluctuations of the calibration setting, mainly at low weight-settings such as those used for treatment of children or in limited weight-bearing with an immediate-post-surgical fitting. Eighteen percent explained that calibration time depended on practice or the kind of patient treated, and 17 percent felt that use of the device was either time-consuming or difficult.
2. *Comments about the Patient-Evaluation Forms:* 10 therapists made separate comments about the evaluation forms (Appendix A:1). Half of them remarked that it was rather long and time-consuming and that they, therefore, tended to estimate some measurements or leave some parts out; 30 percent thought that the forms gave too little information about the patient and wanted to include such things as attention span and a test for endurance; and 20 percent felt that the forms were useful for obtaining a baseline for treatment and for getting a picture of the gait problem.
3. *Comments about Patient Responses:* 20 clinicians commented specifically on patient responses to the device: of these 15 percent explained that patients responded adequately if selected properly.

   Twenty-five percent remarked that the patient category for which the LLM was most useful was the post-surgical fracture patients, and 35 percent stressed that the device was most useful for amputee patients.

   Twenty-five percent felt that patients with hemiplegia in the acute stage would not benefit from the feedback treatment because there were so many other problems at hand at that stage.
4. *Comments about Technical Features:* The majority of comments were made about details concerning the device. Fifteen percent of the therapists wanted a greater variety of insole sizes—either smaller or larger than the full range of sizes they had been provided

with. Thirteen percent were concerned with the quality of the feedback sound which many found irritating or distracting for other patients in the clinic. Other comments dealt with the type and placement of the controls, weight of the box, sensitivity of the setting and price of the unit. The various suggestions about the LLM are listed in Figure 8.

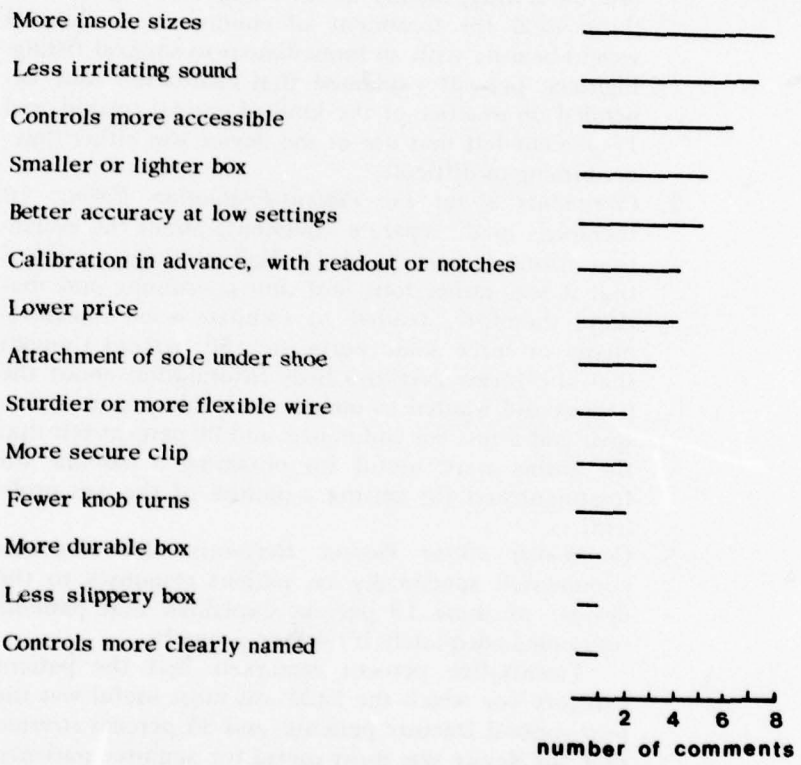

FIGURE 8.—Suggestions for improving the design of the LLM as listed by therapists at the end of the trial. (Length of dash is proportional to number of times each item on this list was suggested.)

Comparison with Questionnaire Responses from Another Group

The LLM has been available for sale at Krusen Research Center for two years, and has been purchased by nine hospitals. Those hospitals had used the LLM for various amounts of time, and without any special introduction or structure. Therapists at those

hospitals were surveyed by mail, using the same questionnaire that was used for therapists participating in the field study.

Results from that mail survey are remarkably similar to those obtained from the field study (10). There were some notable differences, however. For example, the mail-surveyed therapists offered fewer free comments and suggestions, and seemed to be more satisfied with the device as it was, than the field trial participants. For example, in Question 12, which dealt with technical features, 21 percent of the mail-surveyed therapists versus 11 percent of the field trial therapists were satisfied with the device, and in Question 13, which asked about the ease of operation, 69 percent of the surveyed clinicians felt it was easy, versus 49 percent of the trial therapists.

Another difference is seen in the questions that dealt with the type of patients who used the device. The field trial participants' instructions had emphasized selection of amputees or hemiplegics, and still they used the LLM for "other" diagnoses in 11 percent of the answers. The surveyed therapists had used the device in a wider variety of patients and their "other" category occupied 49 percent in the answers. When asked about the group of patients for whom the device might be most beneficial, the majority of each group mentioned the amputees (66 percent and 57 percent) but a considerably higher number of mail-surveyed therapists mentioned "hemiplegics" and "other" categories than did field-trial clinicians. A summary of the responses to the questionnaires is presented in Appendix B.

DISCUSSION

A review of all the results suggests that the transfer of material from the laboratory to the clinic was done successfully and, therefore, that the transfer procedure was adequate. In addition, the results suggest that the LLM is a clinically useful tool. The majority of therapists became comfortable with the device, used it with any patient they felt to be appropriate, and were familiar enough with the concepts to express a multitude of suggestions and feelings about this treatment approach. The comparison of this sample size (81 patients) to the sample size of other field trials which were similarly designed to assess efficacy of a clinical device, is an indication of this study's validity (8). Furthermore, the high percentage of success in achieving goals with this patient sample (79 percent) coupled with the clinicians' positive comments on the clinical utility, support the premise that the LLM is, indeed, a useful clinical tool.

As stated earlier (under *Methods*), this study was a demonstration designed to show that the limb-load monitor could be used clinically to assist in achieving treatment goals. A clinical evaluation of this open-ended type should not be construed as a scientific experimental investigation, for reasons that have been outlined by previous investigators (11). For example, a major source of error consists of the numerous uncontrolled variables which include lack of a control group, lack of a truly random sample, and lack of interrater reliability. Such sources of error may be to some extent unavoidable characteristics of a study such as this. But there were other types of problems which seem to have been built into the process as a result of the clinical study design that was used. These should be given consideration at this point, because it may be completely possible to mitigate or eliminate them in future clinical trials.

For example: it was difficult to establish guidelines regarding how much clinical time and effort should be specified for the device assessment project in place of, or in addition to, the usual staff responsibilities, and for this reason the actual time that each therapist did spend with the device became a point of investigation in this study. As indicated by the therapists, following the initial period of learning to operate the device and becoming familiar with the evaluation forms, they were able to carry on their routine treatment procedures very much in the usual fashion but with an added treatment tool at their disposal. Therefore, it would be useful to develop a mechanism to deal more efficiently with the "introductory period" of new devices in the future.

Another consideration in this type of demonstration project is whether the clinical staff has appropriate support throughout the trial period. From the reported results, it may be concluded that the Rehabilitation Engineering Center staff and the appointed coordinators adequately transferred appropriate materials and information. Their task involved ensuring that all materials and equipment were available, that the clinic selected had an adequate patient load, and that the therapists were properly trained in the use of the device. Despite this effort, there were therapists who "taught themselves" to use the LLM rather than being taught formally or having access to the manual.

Material or equipment breakdowns that occurred during this period were handled within a few weeks through repairs or replacements. Accordingly, malfunction was not reported to interfere with the number of patients selected in any instance.

Another very important consideration is whether the clinical staff consistently and accurately completed the data sheets required for each patient who used the device (Appendix A:1,2). Although

teaching skills or advice were available to the staff, it became obvious during the trial that some prospective LLM candidates were not being included or not recorded, especially during the first months of the trial. Inadequate record-keeping was confirmed at periodic informal meetings, where various staff members from different facilities reported similar clinical trial experiences.

In summary, it was felt that, with a very busy patient schedule, it is difficult for clinical staff members to take the initial extra time (from patient treatment time) to "practice" with any new device, particularly when (as in the case of the LLM) this also required additional "paper work." The result was that, during the initial practice period with the device, the forms were neglected or discarded because the evaluation procedure seemed cumbersome or because the forms were incorrectly completed.

Need for Workshop-Type Pre-Trial Training Confirmed

It seems evident that most, if not all, of these obstacles could be overcome by direct teaching in the form of a workshop with the physical therapy staff before a clinical trial begins. In addition, this information points to the need for thorough staff introduction to any new device added to the present treatment arsenal—this becomes increasingly important when the correct use of a device requires the understanding of recently acquired knowledge and concepts.

The time span, and number of therapists involved, varied considerably among the clinics. Since no specific number of patients was expected or suggested to the clinicians, the patients selected can be seen as a pseudo-randomly selected cross-section of patients with hemiplegia or lower-limb amputations, with remarkably even distribution between the two target groups and the various sub-group diagnostic categories. This is particularly true with the amputee sub-groups. Among the hemiplegic sub-groups, 60 percent had left-sided involvement and only 39 percent were right-hemiplegics: however, it would be expected that the patients with left-hemiplegia (who have a higher incidence of perceptual problems) might also have a higher incidence of weight-bearing problems (7,12).

There are large differences among the various clinics in the relative use of the LLM (percent of population) as well as the number of LLM sessions per patient. This may reflect the type of facility (Table 1) and thus may correspond to the goal of therapy as well as to the patient category utilized. This premise is supported by an examination of results in relation to the type of facility: for example, the two departments with the highest relative number of amputees selected (U. of I., Cook County) are similar in type, each

with a program of acute care as well as a total rehabilitation program for the amputees. Compared to the other facilities, the number of treatment sessions is moderate to large, which reflects the total care treatment approach.

At WWRC patients are admitted primarily for vocational rather than physical rehabilitative goals. Here, again, the large number of treatment sessions administered is consistent with the long-term-care type of facility.

The low relative use of the LLM at RLAH may be correlated to the fact that this facility specializes in treating the "problem" patients with amputation; i.e., those with secondary complications, a fitting problem, etc.

The relative use of the LLM was equivalent at the two children's hospitals (Harvard-M.I.T. and OCCC) i.e., 29 percent and 30 percent of the total amputee population, respectively. The number of LLM sessions at these two facilities was never more than two per patient. Perhaps these results reflect the fact that the children with amputations were seen as outpatients for fitting of the prosthesis and were not reported to be as hesitant about loading their limb as many elderly patients.

The relative use of the LLM for hemiplegia patients is also fairly even between centers. Except for the facilities with non-acute patients (WWRC and OCCC), the number of sessions tends to be lower than that of the amputee target group. This is explained by many therapists as due to the fact that, in the case of acute stroke patients (and in contrast to the patient with an amputation) there are many aspects other than weightbearing and posture that have a higher treatment priority (Fig. 3 and 4).

The number of patients selected to use the device as compared with the number of possible patients in each target group was calculated to be rather low; i.e., one new LLM candidate would be selected by each staff therapist every month. The clinical reality is naturally different, since the bulk of the selected patients in this study were treated by a few appointed therapists who carried the desired patient load and assumed responsibility for the study activities. The average number of sessions at which each therapist used the LLM varied according to type of clinic (Table 4), but for the number of patients per therapist selected, the average was very similar among departments and actually coincided with the result of an earlier clinical trial done with a prototype of the LLM (13). In Figure 9, the distribution of patient work over the trial period is displayed along with the number of clinics involved each month.

For accurate prediction of the expected use of the LLM in any type of clinic, consideration must be given both to the size of the

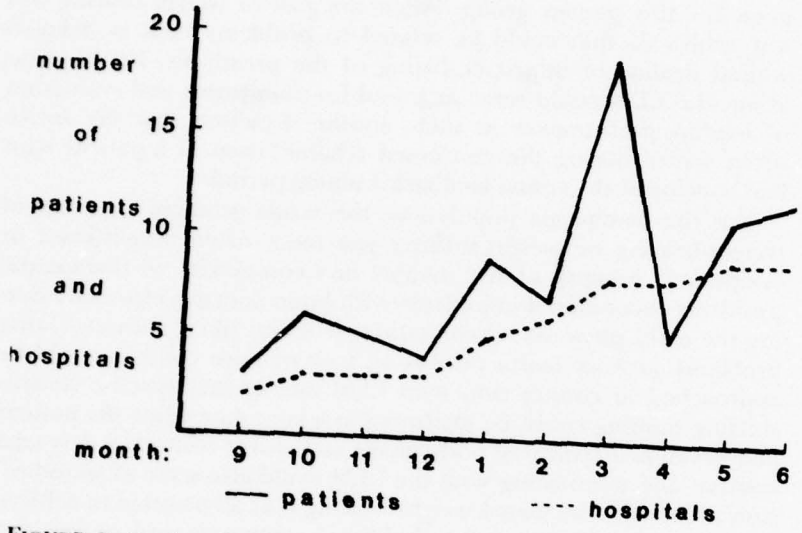

FIGURE 9.—Number of patients seen and hospitals involved per month over the trial period.

staff and to the target population. In counting population, in addition to patients with amputation or hemiplegia, orthopedic patients with prescribed control of loading were suggested by the therapists to be a population which would benefit from LLM treatment (see Results and Appendix B). This is supported by the results of our earlier clinical trials in which patients with limb fractures and total joint replacements were reported to benefit from use of the LLM (8, 13).

It is not uncommon to find physical therapy departments with standard pieces of equipment about which no one knows the frequency of use, or the device's subjective or objective value to treatment. Future studies should attempt to assess the relative use of any new device with various patient categories. This type of information would aid the clinician's decision of whether or not a device could be useful to the particular patient population seen in that facility. Until such studies are conducted, the clinician is forced to continue to select equipment based on tradition and intuition.

Not all patients selected for LLM training could benefit from this approach to weight-bearing training. The highest percentage of positive results was achieved among the amputee patients, which might be expected in view of the fact that proper weight-bearing on the prosthesis is a major goal in itself within the rehabilitation pro-

gram for this patient group. When the goal of weight-bearing was not achieved, that could be related to problems such as delayed wound healing or improper fitting of the prosthesis. In this situation, the LLM could serve as a tool for monitoring and evaluation of loading performance as such, another function that the device often served during the continued rehabilitation of a patient who had concluded the actual feedback training period.

For the hemiplegia population, the result achieved in terms of weight-bearing or weight-shifting was more often insignificant or temporary, because of the number and complexity of therapeutic problems encountered in patients with brain damage, especially during the early phase of rehabilitation. It seems likely, however, that problems such as faulty posture or lack of knee control, could be approached in conjunction with LLM use, or that specific weight-shifting training could be instituted at a later date when the patient had developed improved body image and motor control. A few trial sessions and monitoring with the LLM could also serve as an indication of whether increased weight-bearing is at all possible to achieve in some cases. Many of the clinicians' comments and suggestions in this area may serve as a basis for further studies, and for teaching and introduction of feedback therapy with the LLM.

When a comparison was made between the field trial questionnaire answers and the same questions used in a hospital mail survey, the answers dealing with treatment instructions and patient use were very similar between the groups, but the opinions about general usefulness varied somewhat (Appendix B). The response rate to the mail survey was high (64 percent) but it is very likely that the clinics which responded were the ones which had actively used the LLM the most, had investigated its possibilities and, therefore, approached the structured situation established for the formal trial sites. In comparison, the therapists who participated in the formal trial were forced to use the device with specific patient types, required to fill in forms, and constantly had to comment on the device utility. And, yet, if one considers that 36 percent of the mail-surveyed therapists did not even respond, the results of the formal trial are more positive than the results from the mail-surveyed therapists. Perhaps this is additional support for the need to have some type of workshop where clinicians can become familiar with the device operation.

CONCLUSION

Based on records of 81 patients who used the LLM, and on questionnaire answers and comments from clinicians, the following can

be concluded:

1. The LLM can be operated easily after a minimum of training. It does not break down with extended clinical use when handled properly.
2. The LLM manual provides sufficient information for proper operation and clinical use of the device.
3. The number of patients in a clinic who can benefit from LLM training can be predicted, if consideration is given to the type of facility and the size of the patient population and physical therapy staff.
4. The largest diagnostic group of patients who can benefit from LLM therapy are lower-limb amputees, followed by hemiplegic and orthopedic patients.
5. The general selection criteria outlined initially proved sufficient. A patient who is selected properly can be expected to respond to the feedback signal (i.e., make a weight-bearing adjustment) within the first or second session.

RECOMMENDATIONS

1. The LLM as a device: If possible, the type of sound should be less irritating, the controls should be more accessible or of different design, and the calibration should be more accurate at low settings.
2. Information: For immediate and optimal use of the device, direct teaching in the form of clinical workshops or a cassette slide show should be available to purchasers.
3. Further studies should be initiated regarding the quantity and quality of use (in general) of clinical equipment and procedures.
4. There are several other commercially available devices designed to indicate loading level to the patient. A study should be conducted to assess the validity of, and compare the utility of, these devices.
5. The clinicians selected to participate in a clinical evaluation study should be thoroughly aware of the purpose of the project. The procedures expected of the clinical staff involved should be outlined. Sites should be geographically close to the original center to ensure maximal support to the staff.

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APPENDIX A

Appendix A:1 KRUSEN CENTER FOR RESEARCH & ENGINEERING
LLM
PATIENT EVALUATION

I. Criteria for participation. All seven should be positive:

1a Hemiplegia ☐
1b Amputation ☐
2 Adequate Hearing ☐
3 Comprehension ☐
4 Has no preventive condition (Heart-Lung, Amp./Hemipl., Other Neur.)
5 Asymmetry in walking or standing ☐
6 Can sit without any support 1 min. ☐
7 Can stand with assistive device 1 min. ☐

II. Special patient information:

Code _____
Side of Involvement _____
Onset Date _____
P.T. Discharge Date _____
Complications during hospital stay _____
Age _____
Therapy Goal _____
Primary Diagnosis _____
Orthosis or Prosthesis Type: _____
P.T. Admission Date _____
Outpat. Therapy time: (From-To) _____
Body weight _____ Height _____

Date: _____ First/Second Evaluation

III. Symmetry Evaluation:

Walking

1. Assistive Device
   - parallel bars or walker ☐
   - q-cane or crutches ☐
   - straight cane ☐
   - nothing ☐

2. Average Loading (Norm:100%)
   - less than 70% of bw ☐
   - 70% - 85% ☐
   - more than 85% ☐

3. Velocity (Norm:1m/sec)
   - less than 0.3 m/sec ☐
   - 0.3 - 0.7 m/sec ☐
   - more than 0.7 m/sec ☐

4. Single support time (Norm:35% of stride)
   - extremely uneven gait, less than 10% of stride ☐
   - uneven gait, 10% - 25% of stride ☐
   - almost normal, more than 25% ☐

Standing

5. Assistive Device
   - person ☐
   - parallel bars or walker ☐
   - q-cane or crutches ☐
   - cane ☐
   - nothing ☐

6. Comfortable straight loading on inv. leg loading in lbs: (Norm: 43-57%)
   - less than 30% of bw ☐
   - 30% - 43% ☐
   - 43% - 57% = even ☐
   - more than 57% ☐

7. Maximal loading on inv. leg (Norm:100%) loading in lbs.
   - less than 40% ☐
   - 40% - 60% ☐
   - 60% - 80% ☐
   - more than 80% ☐

8. Endurance Walking
   - only few steps ☐
   - about 100 ft. or functional indoors ☐
   - less than 1 block outside ☐
   - more than 1 block outside ☐

Appendix A:2

KRUSEN RESEARCH CENTER

LLM

DAILY TREATMENT RECORD

NAME_____ DIAGNOSIS_____ INSOLE SIZE_____

Target Function Check One	Treatment Approach Check One	Mode Selection Check One	Treatment Goal Check One
Insuff. loading during walking....☐	Walking.....☐	2 ☐	Increased loading in walking.....☐
Insuff. loading during standing...☐	Prolonged standing.....☐	3 ☐	Full loading walking.....☐
Other.....☐ .....☐	Weight shift for maximal load..☐	window ☐	Symmetrical standing.....☐
	Weight shift around optimal load..... ☐	Other.....	Other..... .....☐

PROGRESS RECORD:

Date	Time Used	Weight Calib.:	Assistive Device	Changes & Comments

APPENDIX B

A total of 36 clinicians responded to the questionnaire from the clinical trial study group and 40 clinicians responded to the questionnaire from the mail survey group. The percentage of each sample who responded to a specific question is listed to the right of that question in the presentation of the questions and responses which follows.

KRUSEN RESEARCH CENTER

Physical Therapist's Evaluation of the LLM

This form has been designed to learn your opinion of the LLM as a treatment tool. LLM utility is based on its ease of operation, reliability, and its usefulness in helping achieve treatment goals. Please be honest with your remarks regarding the LLM and don't spare our feelings. Your input will be instrumental in helping us specify the utility of this device.

Please circle one answer to each question unless otherwise specified:	PERCENTAGE	
	Study Group	Surveyed Group
1. What did you think of the quantity of material contained in the instruction and treatment manual?		
a. I never saw the manual.	17	23
b. I never read the manual.	22	3
c. The manual provided adequate material to allow me to operate the LLM.	58	61
d. The manual provided too little material to allow me to understand the operation of the LLM.	0	10
e. The manual provided much more material than was necessary to understand the operation of the LLM.	3	3
2. How was the clarity of the instruction in the treatment manual?		
a. I never saw the manual.	17	20
b. I never read the manual.	22	5
c. The material had to be read several times before it could be clearly understood.	33	35
d. The material had to be read once and was easily understood.	28	40
e. No matter how often I read the manual, I couldn't understand some of it.	0	0
3. How did you learn to operate the LLM?		
a. I taught myself.	25	32.5
b. Another therapist demonstrated its operation and application.	53	57.5
c. A doctor showed me how to operate it.	0	0
d. Other (specify):	8	5

	Study Group	Surveyed Group
e. I attended the workshop in Philadelphia.	11	.25
f. The Krusen people taught me during a visit here.	3	0
4. What did you think of the quantity of evaluation items that had to be completed for each patient?		
a. Too long.	31	N.A.
b. Too short.	8	N.A.
c. Adequate.	53	N.A.
d. I never used the evaluation forms.	8	N.A.
5. What did you think of the quality of the patient evaluation forms?		
a. Very subjective.	6	N.A.
b. Somewhat subjective.	24	N.A.
c. Somewhat objective.	46	N.A.
d. Very objective.	24	N.A.
5. Did the patients selected relate the auditory signal to performance?		
a. Never.	0	3
b. Always.	53	47
c. Sometimes.	47	50
7. Was an insole (transducer) available in the appropriate size when needed for a patient?		
a. Never.	0	5
b. Always.	56	63

	Study Group	Surveyed Group
c. Sometimes.	44	32
8. Was a working control box available when needed for a patient?		
a. Never.	0	8
b. Always.	69	57
c. Sometimes.	31	35
9. When you were first learning to use the LLM, how much time did it take to calibrate the device?		
a. Limited time (less than 5 minutes) with minimal loading and unloading of the patient's designated limb.	28	36
b. Required at least 5 to 10 minutes of continuous loading and unloading of the patient's limb.	58	51
c. Required more than 10 minutes and patient had to rest before calibration was complete.	14	13
10. After you practiced calibration procedures, how much time did it take to calibrate the device?		
a. Limited time (less than 5 minutes) with minimal loading and unloading of the patient's designated limb.	81	76
b. Required at least 5 to 10 minutes of continuous loading and unloading of the patient's limb.	19	19
c. Required more than 10 minutes or more and patient had to rest before calibration was complete.	0	5

	Study Group	Surveyed Group
11. How was the stability of calibration during one treatment session?		
a. Unstable - patient changed calibration.	8	3
b. Unstable - reason unknown	39	34
c. Stable - stayed at the same weight during session	39	45
d. Never checked	14	18

12. Would a change of any of the following factors enhance acceptance of the device? (Circle as many as are applicable):

	Study	Survey		Study	Survey
a. Color	a. 0	0	f. Sound	f. 28	34
b. Texture	b. 5.5	0	g. Odor	g. 2	-
c. Size	c. 13	6	h. Position of unit	h. 5.5	13
d. Cable (wire)	d. 11	24	i. Shape	i. 7	3
e. Weight	e. 17	18	j. No changes	j. 11	21

13. Regarding ease of operation, do you feel that the LLM		
a. Operates adequately with ease.	48.5	69
b. Should be easier to operate.	45.5	26
c. Is extremely difficult to use adequately.	6	2.5
d. Is impossible to use adequately.	0	2.5

	Study Group	Surveyed Group
14. Did the patients accept the LLM as part of the treatment program?		
a. All.	30.5	35
b. Nobody.	5.5	0
c. Most of them did.	61	60
d. Only a few did.	3	5
15. On the average, when selected to use the LLM, did the patient		
a. Use the device in daily treatment.	46	46
b. Use the LLM about three times per week in treatment.	43	43
c. Use the device about once per week in treatment.	11	11

16. In addition to yourself, who else applied the LLM to your patients (circle as many answers as appropriate)?

	Study	Survey		Study	Survey
a. Family member	5	5	f. P.T.	46	54
b. P.T. Aide	14	26	g. O.T.	0	5
c. Patient	19	15	h. Physician	0	5
d. Orderly	0	5	i. Other (specify)	16	21
e. Nurse	0	8			

	Study Group	Surveyed Group
17. On the average, was the LLM used (circle as many as are appropriate):		
a. Only in the clinic.	81	72
b. In the clinic and on the wards.	5	26
c. Only on the wards.	0	0
d. "Day room" or lounge.	0	0
e. Going to meals.	0	10
f. Outdoors.	0	8
g. Indoors.	7	15
h. Other (specify):	7	3
18. Did patients selected consistently load their limb to the desired level?		
a. Most patients - most of the time.	59	58
b. Some patients - all of the time.	14	21
c. All patients - all of the time.	8	0
d. Most patients - none of the time.	11	5
e. Other (specify):	8	16
19. With what categories of patients did you use the LLM?		
a. Amputees (lower limb).	50	74
b. Patients with hemiplegia.	39	56
c. Other (specify):	11	49
20. If you used the device with more than one category of patient, was the LLM more useful for one group?		
a. Yes - amputees.	66	57

	Study Group		Surveyed Group
b. Yes - hemiplegia.	7	24	24
c. Yes - other (specify):	0		19
d. No.	27		N.A.
21. In general, how long did it take the usual patient to respond to the LLM?			
a. During the first or second session.	91		90
b. Not until the third session.	9		5
c. It took more than one week of continuous treatment for the patients to respond.	0		5
22. Thinking back over <u>all</u> the patients you saw in the test period, roughly what % were LLM candidates?			
a. Less than 10%	37.5		45
b. About 10 - 25%.	34		27
c. About 25 - 50%.	12.5		15
d. More than 50%.	16		N.A.
23. Would you suggest purchasing the LLM for use in your Physical Therapy Department?			
a. Definitely not.	3		0
b. Probably not.	23		11
c. Maybe - depends on: (comment please).	23		21
d. Yes.	51		68
24. What else should we know about application of the LLM in your facility?	Comments on 81% of answers of <u>Study</u> Group questionnaires		

25. On a scale of 1 - 7 (7 is highest), how would you rate the LLM on: (circle one for each column):

See Fig. 7.

	Ease of Operation	Reliability	Use for P.T. Goals	Patient Acceptance
Highest	7	7	7	7
	6	6	6	6
	5	5	5	5
	4	4	4	4
	3	3	3	3
	2	2	2	2
Lowest	1	1	1	1
Study Group	$\bar{X}$ 4.7	4.5	5.1	5.3
Survey Group	$\bar{X}$ 4.9	4.5	5.2	5.4

AN OCCIPITO-ZYGOMATIC CERVICAL ORTHOSIS DESIGNED FOR EMERGENCY USE—A PRELIMINARY REPORT

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INTRODUCTION

The purpose of this paper is to present an original, efficient, non-invasive cervical immobilization device, that can be applied to the patient at the scene of an accident to minimize transportation-induced secondary trauma. This device is to be used as a first step during immediate evacuation, and may remain in situ when emergency X-rays are taken. The metallic components will not obstruct a properly directed X-ray beam.

Statistics quoted by Pierce and Nickel (1) define the need for such a device: "There are probably upward of 10,000 cord injuries that result in paraplegia or quadriplegia each year in the United States and there are probably in the neighborhood of 200,000 paraplegic and quadriplegic patients presently living in this country." These authors further point out that one in every ten patients "has shown progression of symptoms of spinal cord or nerve root damage between the time of initial diagnosis at the scene of the accident and the beginning of definitive in-hospital treatment." These same authors further state that "*first-aid treatment of patients with spinal injuries is at present woefully inadequate* (italics ours) and, if it were adequate, it could in many cases prevent permanent sequelae or reduce neurologic residuals."

DESCRIPTION OF THE ORTHOSIS

Basic Features of Existing Orthoses

Non-invasive orthotic devices provide relatively ineffective immobilization of the cervical spine. A recent study (2) concluded that "lateral bending and rotation over the entire cervical spine as well as flexion-extension at the upper levels were not well controlled by any of the conventional orthoses," and that "the standard orthoses with mandibular and occipital supports are not well suited to controlling lateral bending or sagittal plane motion of the head."

Cervical orthoses (other than those that cannot be applied in the field, such as the halo) depend upon several points of support, the occiput and mandible superiorly, and the shoulder girdles and trunk inferiorly. The soft cervical collar is essentially a reminder orthosis rather than a supportive device (2), because the soft components cannot resist pressure distortion. Other conventional, readily applicable, non-invasive orthoses such as the four-poster and the SOMI (Sternal-Occipital-Mandibular Immobilizer) (2) are fabricated with rigid components, but such orthoses should not be locked rigidly against the mandible during transportation of the cervical-spine-injured patient because of the danger of interfering with respiration as well as with the removal of vomitus, and the possibility of inhalation of such material. Even in the alert and fully conscious patient, immobilization of the mandible interferes with feeding and speech. Therefore, existing conventional orthoses are fitted in such manner that the patient can lift his head and chin away from the orthosis support areas and move his neck to a significant degree in all directions. The only orthosis which comes "close to the theoretical total immobilization is the halo cast. It obviously does not totally immobilize the cervical spine but is very efficient" (3).

Basic Features of the New Design

Certain key components of the SOMI (2) orthosis were retained with specific changes aimed at achieving more efficient immobilization, while at the same time freeing the mandible from its traditional role as an orthosis support area. The changes consisted of:

1. Removal of the mandibular component of the SOMI and its replacement with a U-shaped zygomatic component (Figs. 1 and 2), while retaining all other components of the SOMI; and
2. The addition of a cranial vertex component with appropriate strap restraints (Fig. 3), to complement the extension restraint function of the occipital pad. This feature is particularly useful to limit head extension of the supine patient.

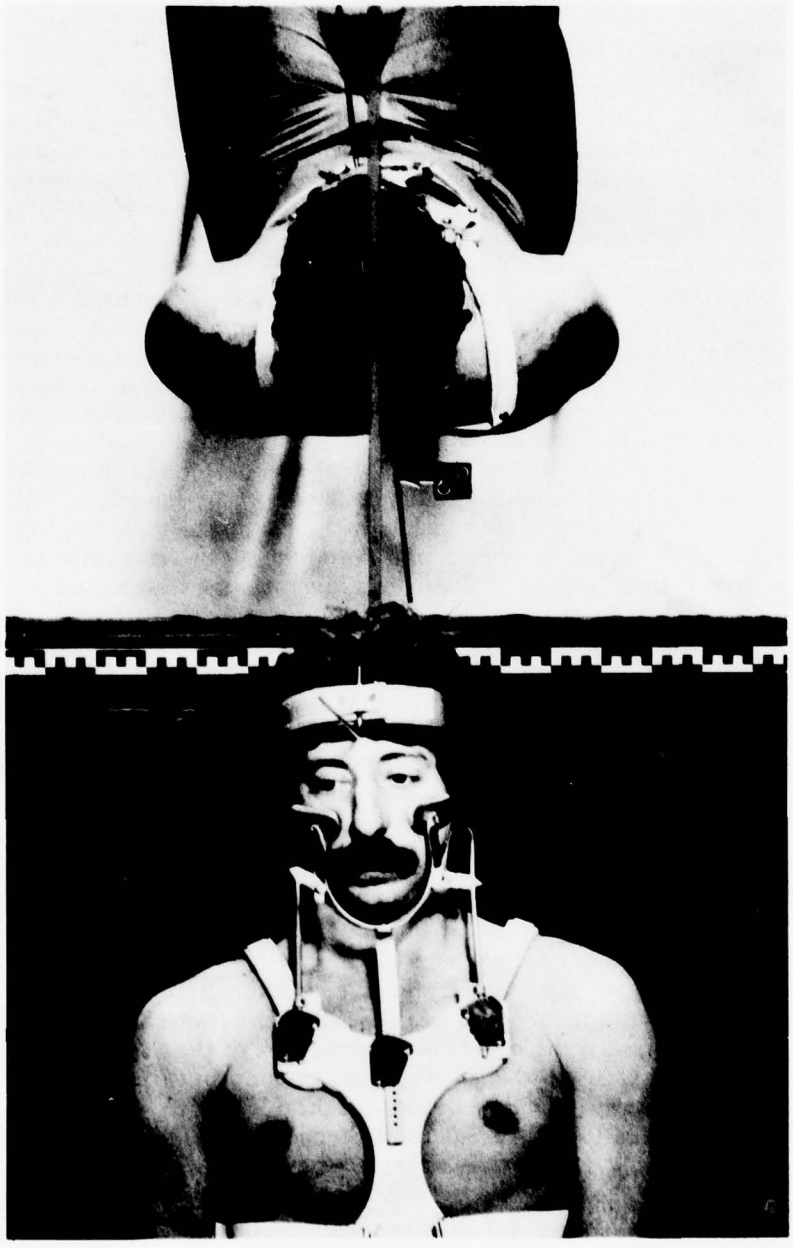

FIGURE 1.—Note the replacement of the SOMI mandibular support by the sub-zygomatic yoke. The range of rotation to the subject's right with the orthosis is shown on the Figure. The subject retained slight movement capability while indicating that the adjustment was not uncomfortable. (This individual's normal range of rotation in the direction shown was measured to be 75°.)

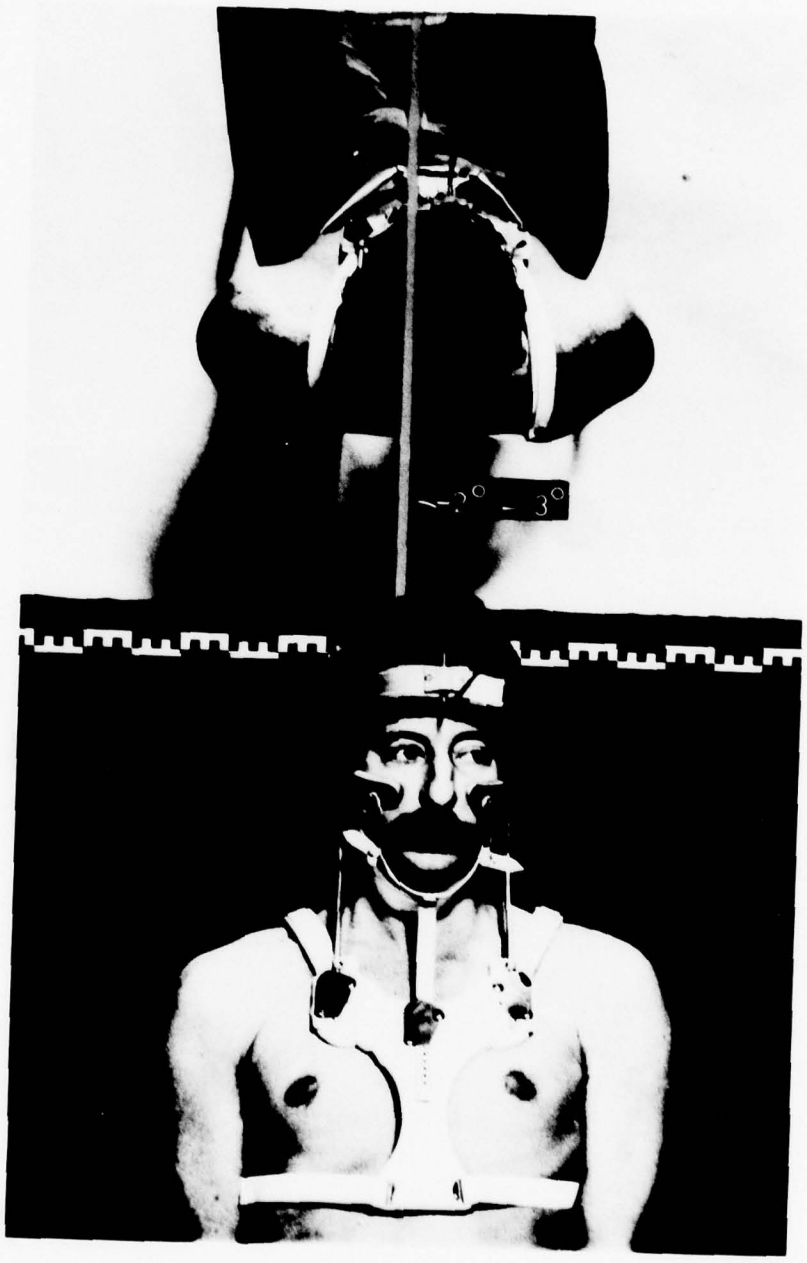
30°
30°

FIGURE 2.—Rotation to left in the orthosis. (This individual's normal range of rotation in this direction was measured to be 75°.)

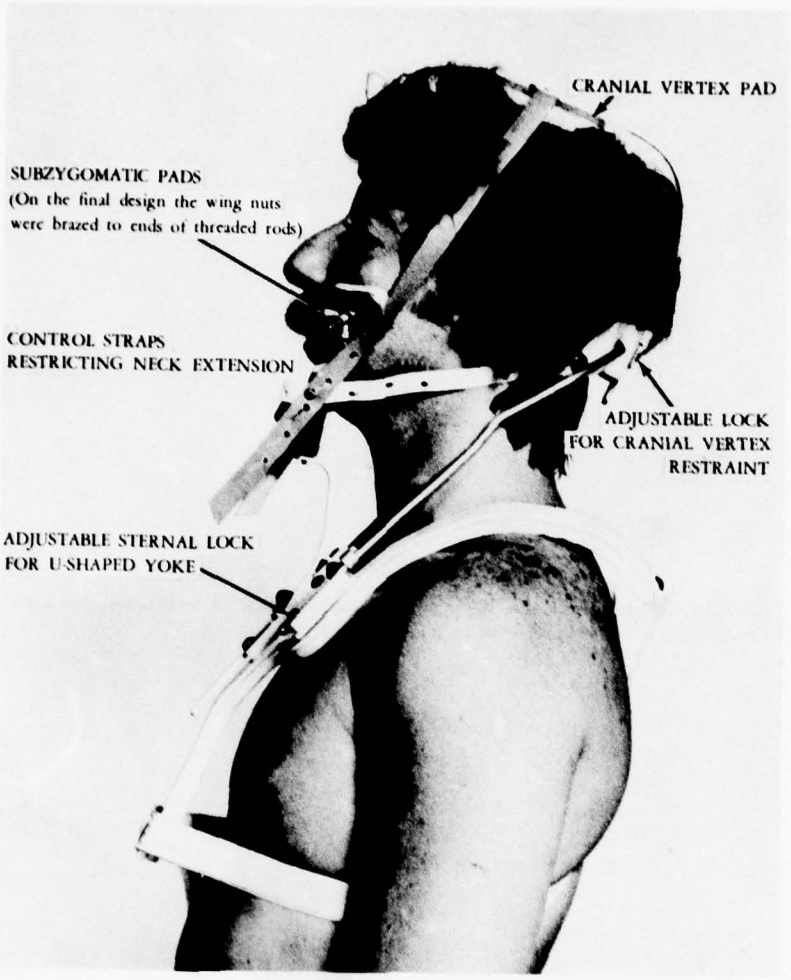

FIGURE 3.—Side view to demonstrate components. Note that there has been no attempt by the orthotist to custom-fit the shoulder/trunk components. Custom-fitting was deliberately avoided in this instance, because it is advised that this orthosis be employed as an emergency application device. In spite of that, flexion and extension are markedly restricted.

Advantages of the New Design

1. The yoke bypass of the mandible to the zygomata allows mandibular motion and permits the patient to open his mouth. The use of the sub-zygomatic support areas allows the orthotist to fabricate padded sub-zygomatic supports which are not only vertically supportive but are also placed obliquely in relation to the sagittal plane to restrain rotation effectively.
2. The pads, which are mounted on ball and socket joints, can be threaded in toward the zygomata or away from them, to accommodate different facial bone measurements.
3. Ease of application is retained. During application "gentle axial traction" (1) should be maintained by placing the hands on the chin and occiput. The orthosis can be applied over the patient's clothing in the manner of the application of the SOMI. The orthosis should be applied in four steps by two trained ambulance attendants. One attendant must maintain head traction with the patient in the supine position until application is completed. The four sequential steps are as follows:
    1. The trunk (shoulder-sternal) component is applied first and the criss-crossed straps are pushed beneath the patient to their anterior attachments points, and tightened.
    2. The occipital component is then fitted into place, vertically adjusted, and locked into the appropriate locks.
    3. The zygomatic yoke should next be positioned in the sternal slot and locked. The pads should be adjusted into the subzygomatic recesses by turns of the wing nuts. A final vertical readjustment of the yoke may be required.
    4. Finally, the cranial vertex component should be fitted snugly to the vertex and fixed in position in the lock. (Fig. 4).

Retention of the SOMI Design Principles

The original SOMI was designed to permit its application to the supine patient with minimal manipulation of the cervical spine. This aim was achieved by carrying the occipital support struts anteriorly to adjustable fixation points (Figs. 1 and 2). A fixation point over the sternal segment of the orthosis was included to allow for vertical adjustment of the mandibular component of the SOMI, which could then be locked into position.

In the present design, after the mandibular component had been removed and replaced by the sub-zygomatic yoke, the sternal attachment point was used in the same manner, i.e., to allow vertical

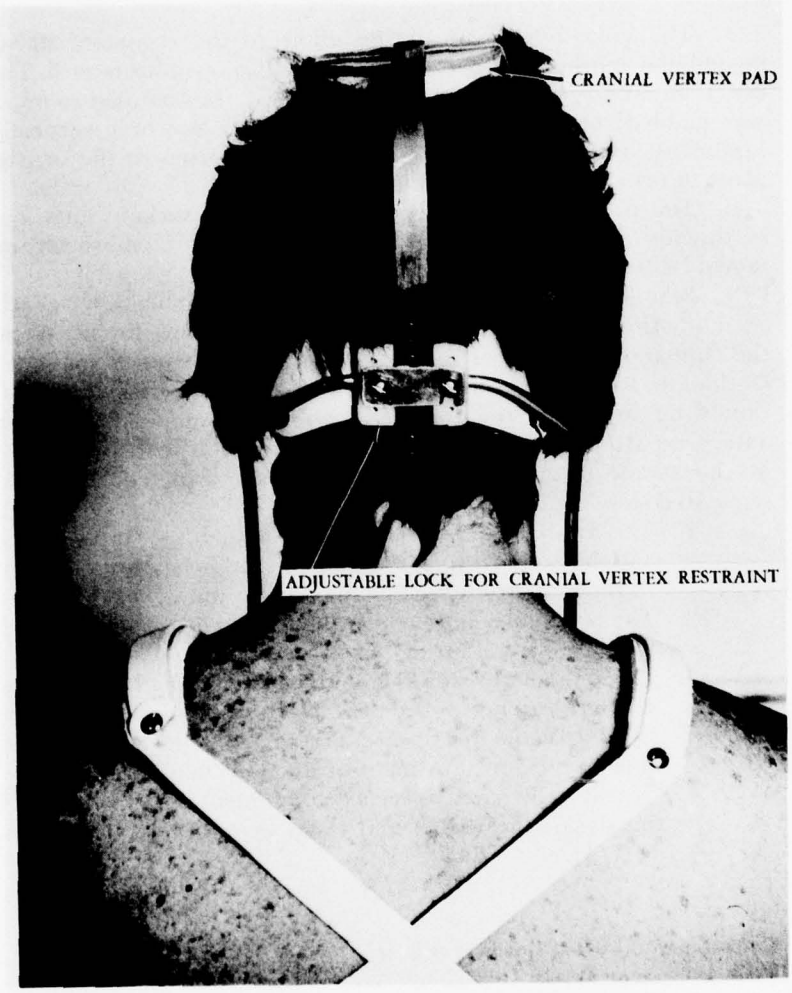

FIGURE 4.—Posterior view to demonstrate a lock for extension restraint.

adjustment and locking of the yoke. Finally, a similar adjustable fixation point was added to the occipital component of the SOMI for attachment of the cranial vertex restraint (Fig. 4). In essence, this device is more rigid than the SOMI (2).

EFFECT OF THE ORTHOSIS ON CERVICAL MOTION

A young, healthy, adult without cervical complaints was used as the subject. The zygomatic pads were adjusted until the subject indicated that they were not uncomfortable.

Head motion was measured in relation to the superior border of the 7th cervical vertebra by drawing a line across the superior border of that vertebra and relating this to a line drawn through two fixed points on the skull: the center of the occipital protuberance and the lower border of the mastoid process:

1. *Flexion* (Figs. 5 and 6)
   a. without the orthosis: 40 deg
   b. with the orthosis: 2 deg-3 deg
2. *Extension* (Figs. 7 and 8)
   a. without the orthosis: 83 deg
   b. with the orthosis: 0 deg
3. *Right Lateral Bending* (Figs. 9 and 10)
   a. without the orthosis: 30 deg.
   b. with the orthosis: 3 deg
4. *Left Lateral Bending* (Figs. 11 and 12)
   a. without the orthosis: 30 deg
   b. with the orthosis: 5 deg
5. *Rotation* – 75 deg in each direction (measured but not photographed). For this individual the range was greater than that recorded in the publication "Joint Motion" of the American Academy of Orthopaedic Surgeons (60 deg) (4).
   a. with orthosis, to right (Fig. 1): 6 deg
   b. with orthosis, to left (Fig. 2): 2-3 deg

INDICATIONS

The authors suggest the use of this new design for emergency application at the scene of the accident to virtually "lock" the head and neck into almost total immobility and limit the possibility of additional secondary iatrogenic damage to the already traumatized neck. The long term effect of pressure on the sub-zygomatic soft tissues is not known at this time and, for that reason only, prolonged therapeutic use cannot be recommended until such effects can be evaluated. (This device is currently being distributed to several spinal-cord-injury centers throughout the country for their use and evaluation.) Should this orthosis be employed for routine immobilization rather than for an emergency situation, the vertex restraint may be removed and the device may be custom-fitted (see caption for Figure 3).

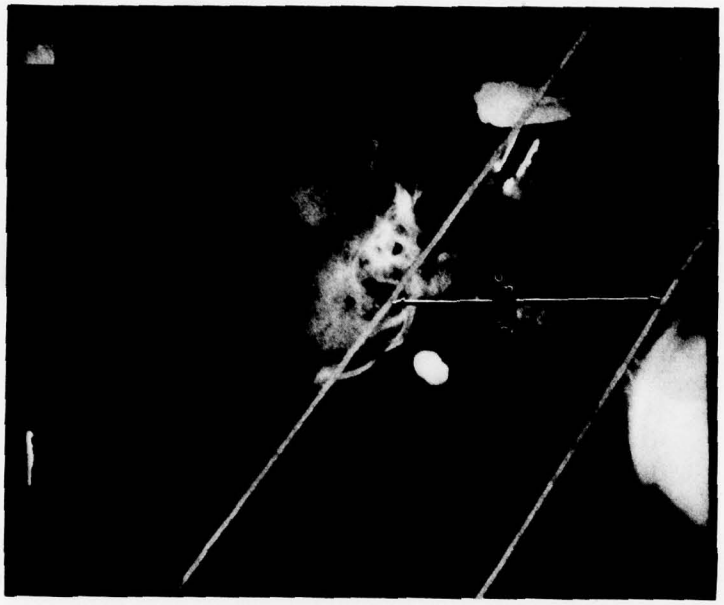

FIGURE 6.—Flexion in orthosis.

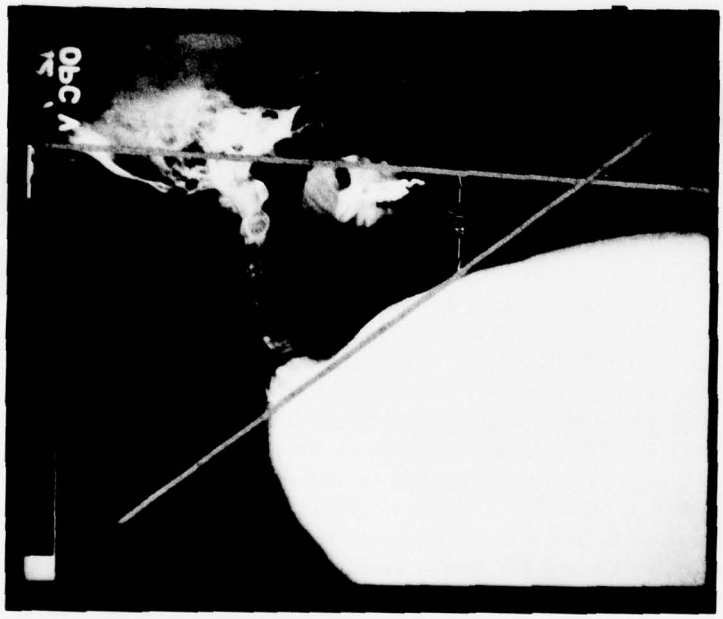

FIGURE 5.—Unrestrained flexion.

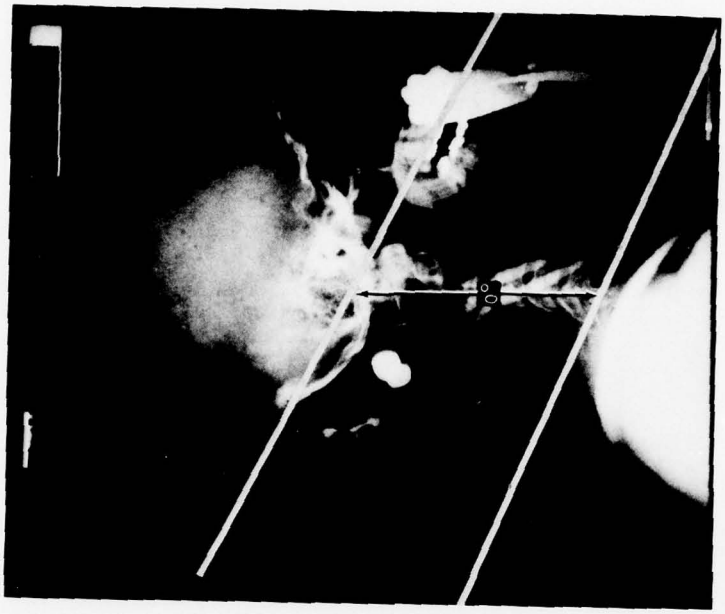

FIGURE 8.—Extension in orthosis. Note that the forceful effort employed by the subject in his attempt to extend caused bowing of the steel head restraint bar.

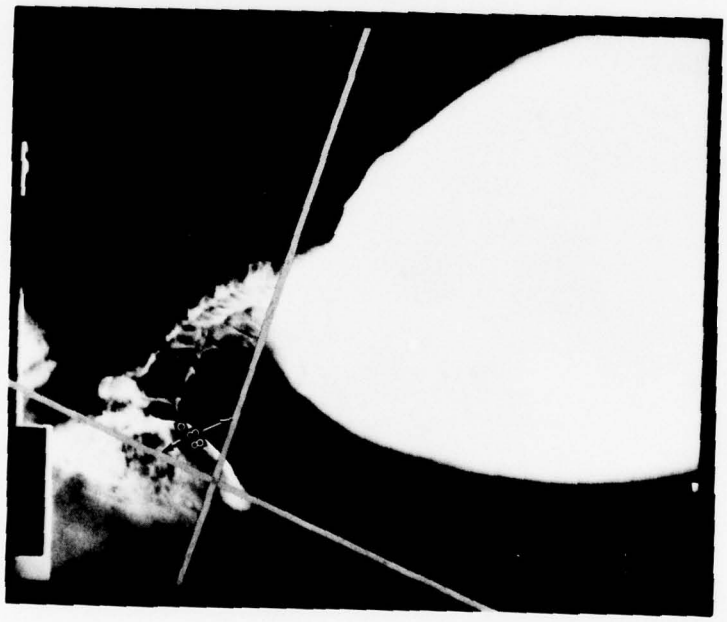

FIGURE 7.—Unrestrained extension.

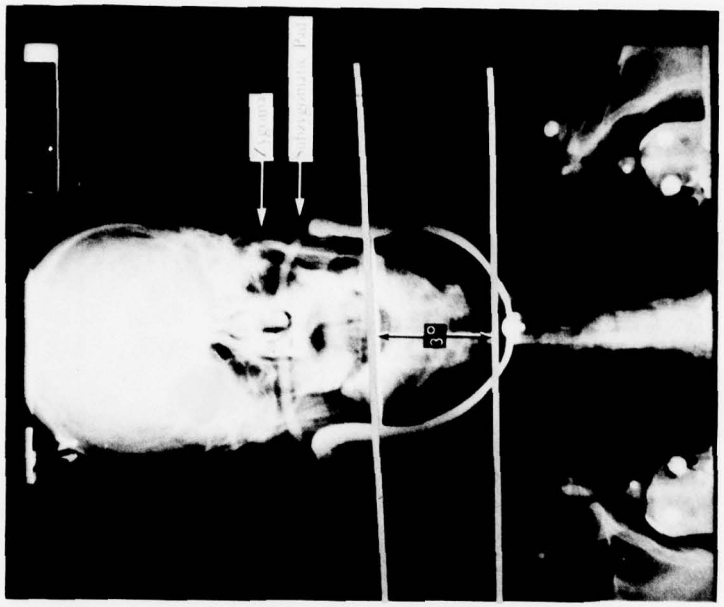

FIGURE 10.—Bending to right in orthosis.

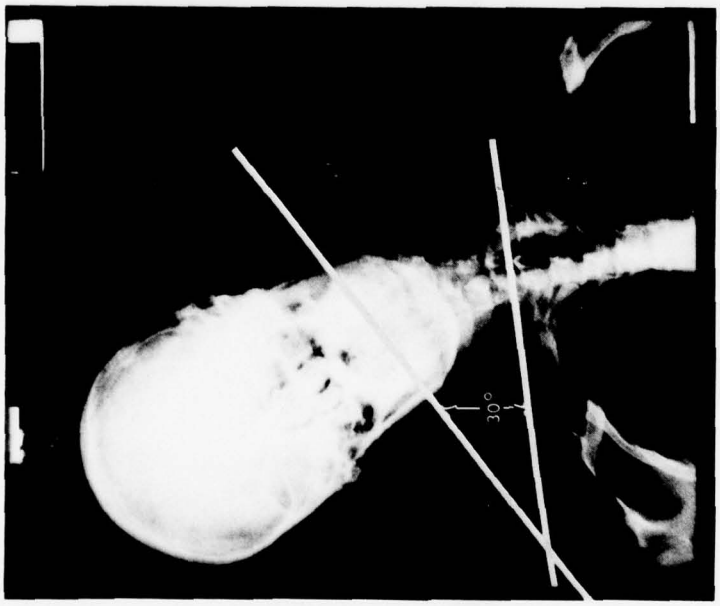

FIGURE 9.—Unrestrained bending to right.

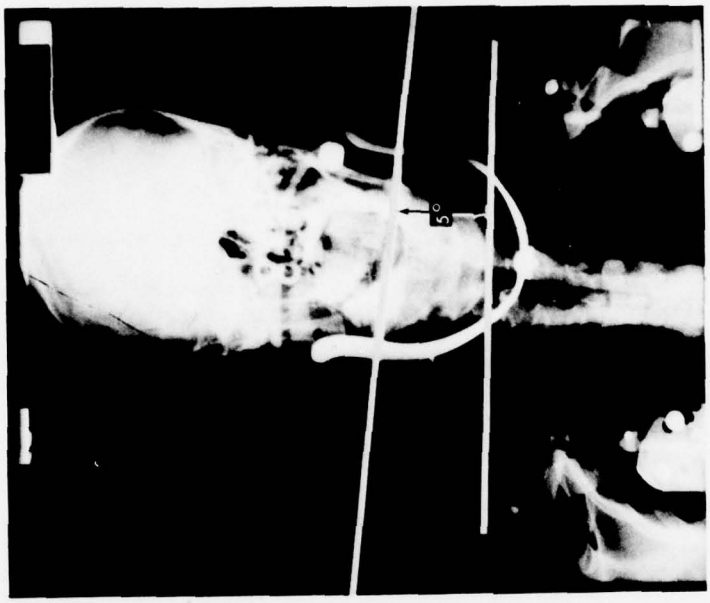

FIGURE 12.—Bending to left in orthosis.

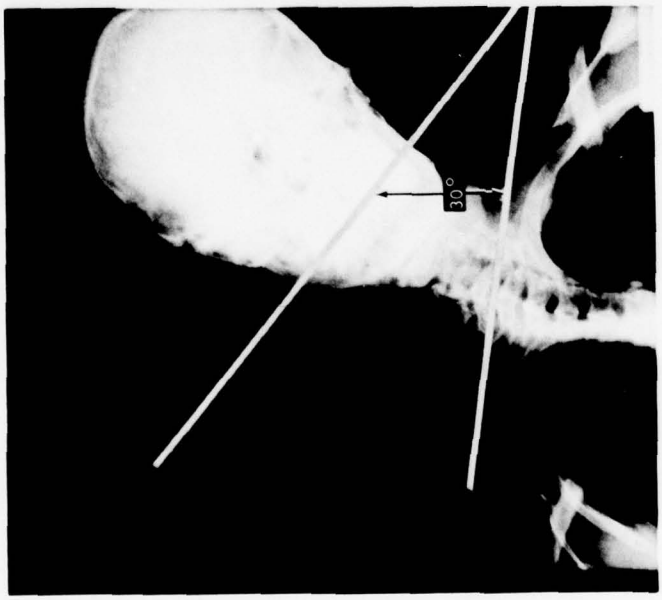

FIGURE 11.—Unrestrained bending to left.

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The authors wish to extend their appreciation to Michael Danisi, C. O. and Eugene Lamberty, C. O. for their contributions to the development of this orthosis.

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4. Joint Motion. Method of Measuring and Recording. Amer. Acad. Orthop. Surg., p. 86, 1965.

Note: For further information, *see also* Boldrey, E.: Supportive Immobilization of the Cervical Spine. J. of Surg., Gyn., & Obst., 80:107-108, Jan. 1945. (This article refers to the use of a custom-fitted orthosis employing the technique of subzygomatic support in a somewhat different manner than that reported here, but using the same principle. The orthosis described by Dr. Boldrey uses extensions passing from the occipital support component laterally around the side of the head to the zygomata. It is of interest that Dr. Boldrey found essentially the same degree of limitation of motion that the authors achieved. It is also of interest that Dr. Boldrey considered it advisable to attempt to fabricate a similar orthosis which could be used in emergency situations.)

EDGE LIGHT: A NEW APPROACH TO STUDYING THE MICROVASCULARIZATION OF THE SKIN[a]

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INTRODUCTION

Clinicians have been interested in investigating capillary blood flow and what affects it, ever since Homo sapiens complained of a blister, corn, tight bandage or cast, or a decubitus ulcer—any condition leading to ischemia with the potential of then progressing to tissue necrosis.

One of the problems in investigating capillary blood flow has been the difficulty of reliable measurement. As a method of measuring small-vessel blood flow, plethysmography is the most direct, but unfortunately it is limited in its applicability (Barbenel et al.,

[a]This research was funded in part by U. S. Public Health Service Grant No. NU 00444: Nursing Measures in the Prophylaxis of Pressure Sores.
[b]Dr. Verhonick died October 1, 1977.

1976). More indirect methods have been used which infer the capillary blood flow through its relationship with temperature, visual appearance of the skin, absorption rates, or pressure. These indirect methods include the use of thermography, thermistors, direct-pressure and interface-pressure instruments, uptake of radioactive isotopes, use of transparent materials to view changes in areas under pressure, and transillumination.

A new technique of modified transillumination, described in this article, was developed using normal healthy adults as subjects. It is noninvasive and does not require the application of instrumentation to the skin surface.

REVIEW OF TECHNIQUES

Thermography

Thermography produces a visual image indicative of the temperature distribution over the skin surface. Areas of the skin that have a normal blood flow have a normal skin temperature, and present a pattern of infrared radiation emitted by the skin surface (Barnes, 1963, 1968). Changes in the blood flow affect the skin temperature and can be detected by a change from the baseline thermographic pattern. Evans et al. (1976) used thermography to study arterial obstruction in the lower limbs: the investigators found that thermography identified the abnormal skin temperature distributions that were due to arterial occlusions in the lower limbs.

Verhonick, Lewis, and Goller (1972) used thermography in studying decubitus ulcers. They used the thermogram to document the effects of body weight pressure (lying on a stretcher) on the knee and heel. Reactive hyperemia, "flushing", was documented on sequence thermograms by a high pressure area showing first as a cold area, then "flushing" to show as a higher-temperature region than surrounding areas, and finally equilibrating back to a near-baseline temperature distribution pattern. In the mentioned study, thermography was investigated as means of quantifying the relationships between body-weight pressure and temperature change.

Earlier, Goller (1971) had established the relationship between temperature change and a known amount of pressure. Kosiak (1961) and Lindan (1961) found the pressures to be most intense when they are related to bony or tendinous prominences; they may exceed 100 mm Hg over these areas. The relationship between allowable pressure and time duration, for "safe" pressure-time support, was published by Kosiak in 1961.

Interface Pressures

Various means of pressure measurement have been used to evaluate interface pressure. No available device is without problems: the reader is referred to Ferguson-Pell et al. (1976) for a full discussion of such problems. Most commonly used devices are either pneumatic or are variations of strain-gage application. Pneumatic sensors, consisting of from one to eight inflatable membraneous cells, utilize electrical contacts within the cells that close at the point where internal pressure equals the interface pressure. Strain-gaged diaphragm transducers measure surface strains by electrical strain gages, but they are rigid, and the dimensions need to be small if they are to be used on curved interfaces. A commercial 'beam' transducer (monolithic strain-gaged beam encapsulated in rubber) was evaluated at Strathclyde (Ferguson-Pell, 1976): it was found that the 'beam' responded to inplane forces as well as to normal forces.

Research into the difficult problem of reliable pressure measurement continues, and includes the use of an elastic disc with which electrical measurements may be made by resistive, inductive, or capacitive techniques.

Other Methods

Other methods of looking at pressure and its effects on the microcirculation involve the use of radioactivity-tagged isotopes. Daly et al. (1976) used $Xenon^{133}$-labeled saline to measure changes in uptake by the microcirculation of the skin in response to pressure. Hickmann et al. (1966), using Na^{24} on the backs of rats and the volar surface of forearms in humans, measured the alteration of skin blood flow caused by pressure. These investigators found that when the pressures approximated mean capillary pressure (25 mm Hg), Na^{24} clearance rates averaged about 80 percent of normal. However, cyclic loading resulted in different effects on capillary blood flow during the loading and unloading phases of the cycle.

Romanus (1976) studied the influence of time, pressure, and temperature on the microvasculature of the hamster's cheek pouch. Repetitive pressure, even though not damaging on single application, produced alterations in blood flow depriving the tissue of normal oxygen levels. Barbenel et al. (1976) attempted to find a load level which was critical for effecting a sudden decrease in capillary blood flow. These investigators used an abdominal fold and the technique of transillumination. Their findings showed no correlation between load levels and the point where blood content of the skinfold suddenly decreased.

That areas of ischemia can be made visible through transparent materials was demonstrated by Miller and Sachs (1974). It is fairly evident, to an observer looking through the transparent material, that the ischemic area is also the point of greatest pressure. The other contact areas of skin, however, do not show any gradations of skin-color change to indicate degrees of alteration of capillary blood flow due to the pressure of body weight.

EDGE LIGHT TECHNIQUE

Verhonick, Lewis, and Kissinger, while working on a protocol to quantify measurement of variables pertinent to the acquisition of decubitus, developed a technique of modified transillumination (edge light) which shows alterations in capillary blood flow in skin-contact areas. With the subject lying supine on a Plexiglas® surface and draped with a dark cover, two photolamps (3400 K) were positioned to allow a strong section of light to pass through the edge of the Plexiglas support surface (hence "edge light"). The refraction of the light passing through the half-inch thick Plexiglas illuminated the skin areas that were in contact with it. As viewed from below, this modified transillumination revealed differences in the color densities (presumedly due to amount of blood flow) of the otherwise uniformly-colored non-ischemic contact area under body weight.

Figure 1 illustrates the appearance of the torso viewed from below by conventional lighting, through a transparent Plexiglas support surface. This type of photograph is similar to those published by Miller and Sachs (1974). Figure 2 illustrates the same subject, again viewed from below through a rigid Plexiglas sheet, but this time the illumination is "edge light" as described earlier.[c] In Figure 3, a piece of thin flexible cellulose acetate has been attached to the underside of the Plexiglas support surface, and on this the pattern of blanched areas that is visible under edge-lighting has been delineated with a "grease pencil." (One-foot rules, supported by the cellulose acetate film, provide a reference scale.)

Figures 4, 5, and 6 illustrate the same situations as Figures 1, 2, and 3, respectively, but with a different subject.

The Attempt to Correlate Visual Contact Patterns with Interface Pressure Data

The rank-order distribution of pressures, as may be inferred from the observation of skin colors while the subject is resting on the

[c] A group of 35-mm color slides, illustrating the edge light phenomenon as described here, is on file at the editorial offices of the Bulletin of Prosthetics Research. Subject to availability, these may be borrowed for study and/or copying.

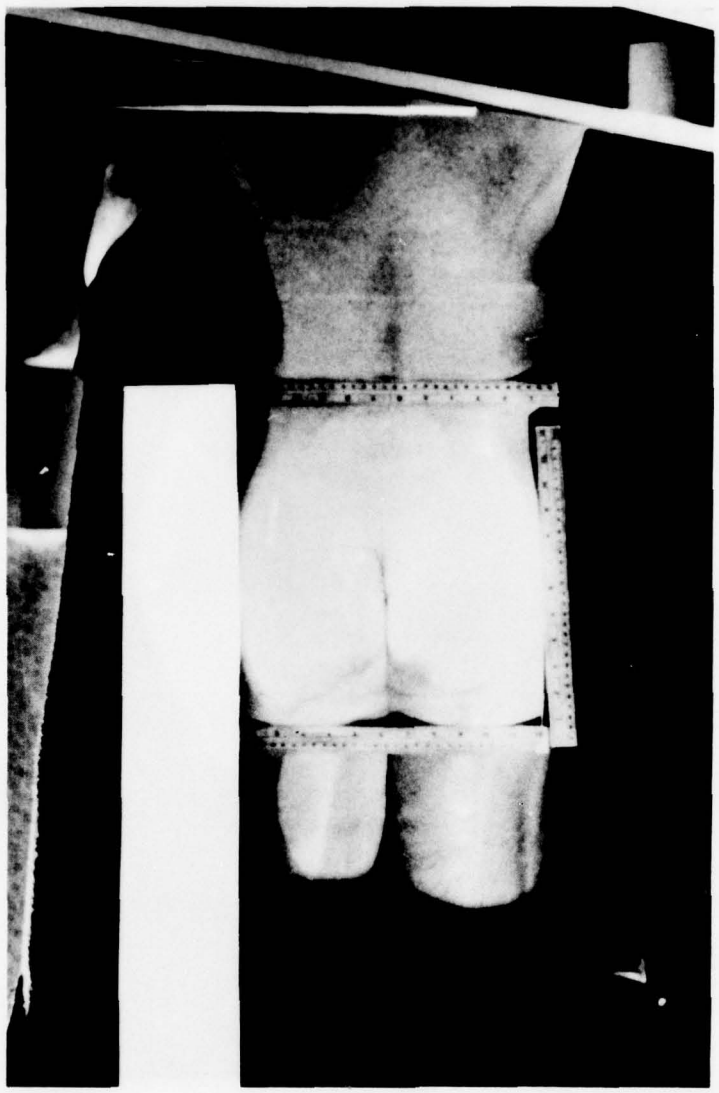

FIGURE 1.–Subject A, shown lying supine on a sheet of rigid (half-inch-thick) transparent Plexiglas®. Subject is illuminated from below with conventional direct lighting: black drapes restrict entry of light from above. Photograph was taken looking upwards through the transparent Plexiglas®.

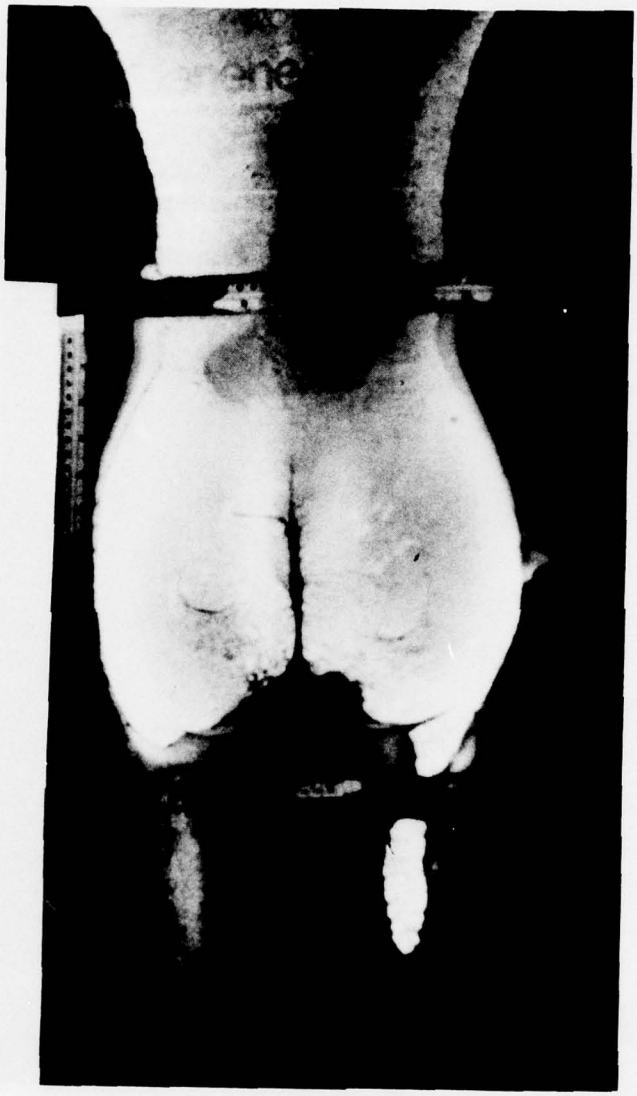

FIGURE 2.—Subject A, arranged and photographed as in Figure 1, except that the illumination is provided by "edge light."

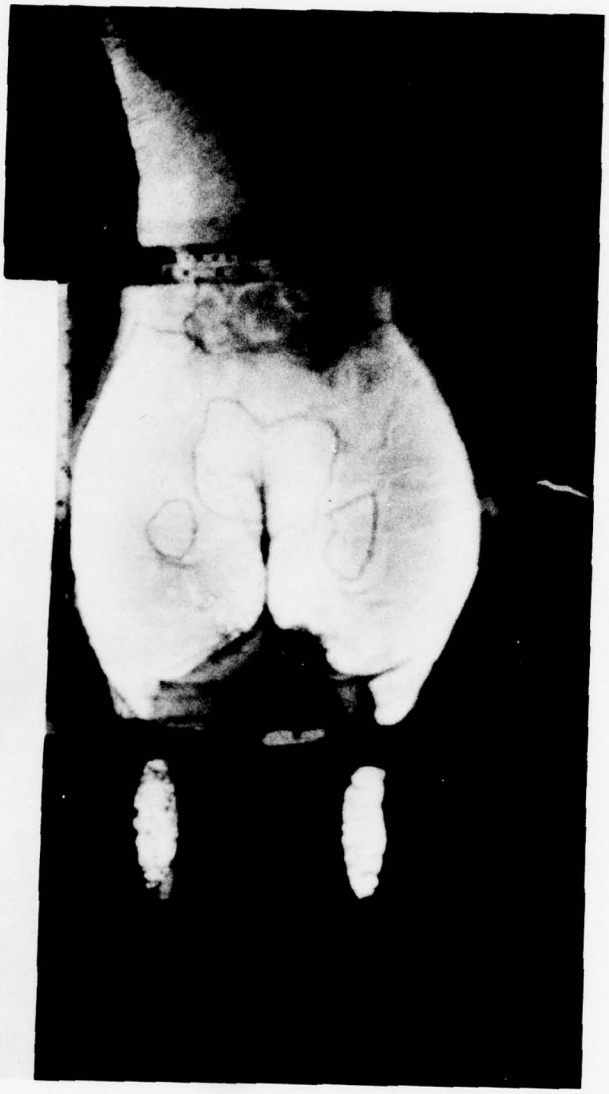

FIGURE 3.–Subject A. A grease pencil has been used to trace the pattern of blanched area boundaries seen only faintly in Figure 2. (These boundaries and areas, clearly visible to the observer with edge light, are somewhat less clearly visible in a good color photograph. Black-and-white photography, however, records only a suggestion of the phenomenon.)

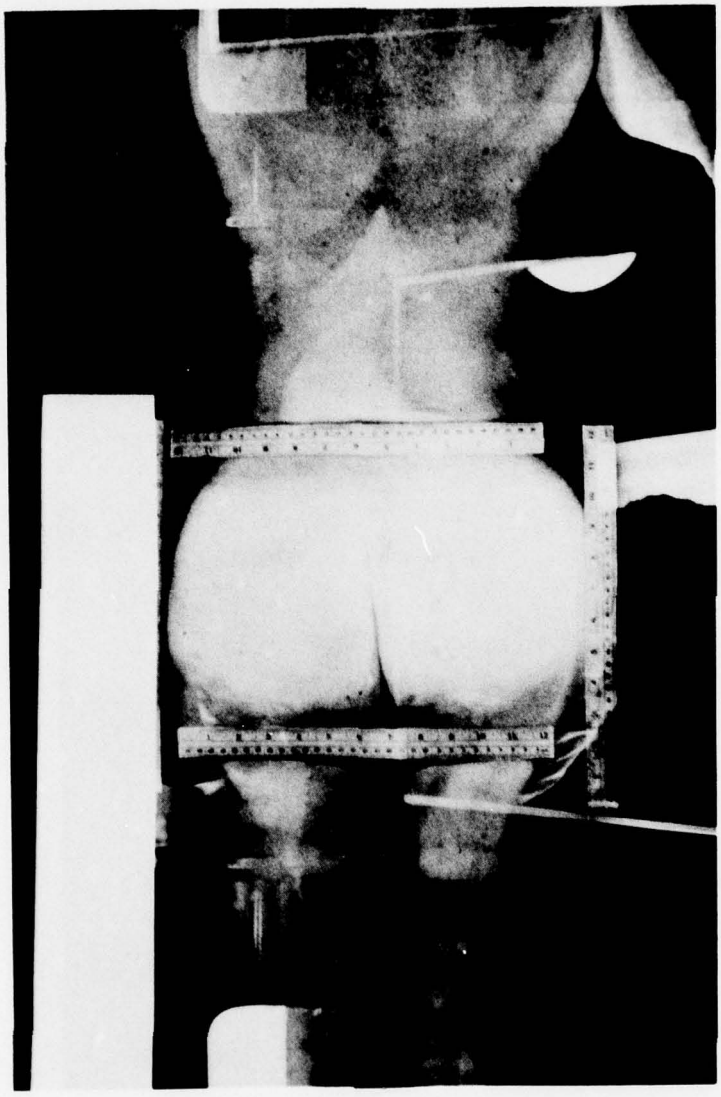

FIGURE 4.—Subject B, photographed under conditions described in Figure 1.

FIGURE 5.—Subject B, photographed under conditions (edge light) described in Figure 2.

FIGURE 6.—Subject B, with pattern traced as described in Figure 3.

rigid transparent Plexiglas sheet with edge lighting, is considered to be a direct indication of the distribution of pressures as they would be with the subject resting on a non-compliant operating table. Thus, this same distribution is also considered to be a useful guide for an experimenter who wishes to locate pressure gages in areas of greatest interest for tests with other supports.

The presence of any gage (regardless of its thickness or compliance) between the body and a noncompliant support will cause an artifactual increase in apparent pressure. At more rigid body tissue (e.g., a bony prominence with very little covering of soft tissue) or for a thicker gage, this artifactual increase will be greater. Conversely, softer and thicker flesh, or very thin gages, or a softer supporting surface, should each provide a smaller increase of recorded pressure above the true pressure. Nevertheless, it may be hypothesized that the *rank order* of pressures distributed over the various body surfaces is preserved in the rank order of the gage readings from those areas.

Based on this hypothesis, the subject shown in Figure 7 was used in preliminary tests. The gage was an inflatable pneumatic membrane cell made of two walls, each flexible plastic .003-inch thick. Pressures were measured between the supine body and a thin foam mattress on the metal plate of a wheeled hospital stretcher. Because the pressure gage was thin and flexible, and because of the use of the foam mattress, the artifactual increase in observed pressure beyond that existing without a gage was considered modest, though there was no direct validation of that opinion. The subject appeared to have interface pressures of 58 mm Hg at body midline on the sacral horizontal line and 66 mm Hg at a point one-quarter of an inch above it. Both pressure values are far higher than capillary blood pressure, which is in general agreement with the severe blanching observed through the rigid Plexiglas sheet. In contrast, the pressure between body and foam mattress at midline 1 inch below the horizontal line was only 30 mm Hg, probably slightly lower than capillary pressure. Looking at the pattern seen on the edge-lighted Plexiglas sheet, one could predict from the dark noncontact area between the buttocks that pressures at body midline would decrease rapidly as one moved the gage downward from the sacrum. Likewise, pressures decreased progressively from the sacrum to the outer quadrants of the buttocks, in the same approximate rank order as the trace contact pattern demonstrated by edge light. (Those patterns are much more apparent to the eye than they are in photographs.)

Obviously, there must be careful placement of the body in the same position and with the same muscle tensions, to permit valid

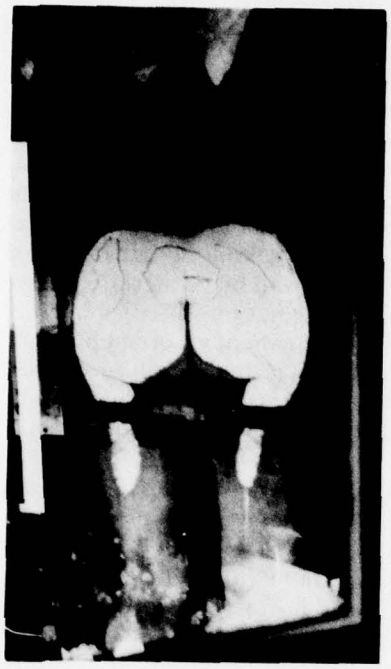

FIGURE 7.—Subject used in preliminary tests with pressure gage, shown here under conditions as described in Figure 3.

comparison between visual observation with edge light on the hard Plexiglas sheet and estimates of pressures from gages at critical locations between the body and the softer mattress.

DISCUSSION

The technique of edge light, and the correlation of the trace contact pattern with interface pressures and thus with alteration of the microvascularization of the skin, has not been studied in a controlled research design with a large number of subjects. However, findings from our study are suggestive that the trace pattern of color gradients revealed by the technique of edge light is inversely related to the pressure gradients, with the lighter-colored contact areas being under greater pressure from body weight than the darker-colored contact areas. It is further suggested that the gradations in color are positively related to amount of blood in the subpapillary venous plexus and capillaries of the skin (Lewis, 1927), with the ischemic pallor indicating cessation of blood flow. Gradations of color ranging from pallor to dark would indicate gradations

of the increasing amounts of blood in the subpapillary venous plexus and capillaries.

Lindan et al. (1965) suggested that the gradient of pressure across contour sites, such as the buttocks, is approximately linear. Newell et al. (1970) suggested that higher gradients exist around bony prominences. The interface pressure measurements and edge light trace patterns as studied by the authors suggest that the pressure gradient across the buttocks contour is not linear, and that the pressure gradient patterns differ depending on individual skeletal and subcutaneous structures.

It is recommended that the technique of edge light be further studied and correlated with interface pressure measurements under controlled conditions. If, on further investigation, edge light continues to disclose subcutaneous irregularities, it is recommended that the technique be explored for use also in detection of breast cancer. From the perspective of the subjects' safety, the technique of edge light has as its assets: noninvasiveness, freedom from instrument attachment, and the lack of exposure to radiation. And, unlike many other investigative techniques in the clinical area, the technique of edge light can be used by non-physician investigators.

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VETERANS ADMINISTRATION PROSTHETICS CENTER RESEARCH REPORT

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I. DEVELOPMENT AND EVALUATION
- A. Prosthetics
  - Lower Limb
    - a. Plastic Knee Joint for Below-Knee Prosthesis
    - b. Graphite-Epoxy Knee Joint
    - c. Nylon Knee Joint
    - d. U.S. Manufacturing Co. Four-Bar-Linkage Knee
- B. Orthotics
  1. Plastic Knee Orthosis
  2. Orthotic Transverse Rotator
- C. Spinal-Cord-Injury Rehabilitation
  1. Environmental Control Systems
     Stanley Silent Swing Door Operator
  2. Communications Aids
     Saltus Reading System
  3. Mobility Aids
     - a. Freewheeler Power Wheelchair
     - b. Electronic Power Conversion Kit for Wheelchairs
     - c. Electric Back-Recliner Kit
     - d. Icarus Easy Transfer Wheelchair Attachment
     - e. Arrow Wheelchair
     - f. Rigal Walker Tray
  4. Body Support Systems
     E-Z Patient Turning System

I. DEVELOPMENT AND EVALUATION

A. Prosthetics

1. *Lower Limb*

a. *Knee Joint for Below-Knee Prosthesis.* Efforts continue to find a suitable plastic knee joint to replace the steel knee joint still being used in below-knee prostheses. The previously described efforts to use polypropylene demonstrated that this material lacks the rigidity required in a knee joint by most thigh-corset wearers (BPR 10-26, p. 216).

b. *Graphite-Epoxy Knee Joint for Below-Knee Prosthesis.* Efforts with graphite-epoxy composite were also unsuccessful, since it has been impossible to shape this material to the contours required.

c. *Nylon Knee Joint.* Currently being evaluated is the use of nylon for this purpose. Initial investigation demonstrated that this material can be shaped at room temperature to the desired contours, and it seems to possess the required rigidity. Nylon knee joints are currently being fabricated and patients will be selected as pilot wearers.

d. *U.S. Manufacturing Co. Four-Bar-Linkage Knee.* This device, developed by the U.S. Manufacturing Co., Glendale, California, makes use of a polycentric four-bar system installed in an endoskeletal prosthesis, with a machine-contoured foam cover. The knee uses mechanical constant-friction to control swing phase. An elastic extension aid is provided. The unit is comparatively light in weight, provides good knee stability, and allows relatively greater knee flexion. It can be fitted to amputations at the knee-disarticulation and above-knee levels.

The knee was fitted to an above-knee amputee who has a fairly long residual limb and evaluated for 1 year. No special problems were encountered by the prosthetist during fitting and fabrication, and time and cost factors were within the allowable range for

standard above-knee prosthesis. The patient's reaction to the unit was favorable: his gait improved due to better knee stability, and it required less effort to maintain a stable knee, as compared to his previous (single-axis) unit.

The knee still functioned satisfactorily after the year of use. The only maintenance required during the evaluation period was the need to replace the worn-out elastic extension aid after 6 months.

B. Orthotics

1. *Plastic Knee Orthosis.* Although we have been successfully fitting polypropylene knee orthoses with suprapatellar strap suspension for more than 2 years (BPR 10-23, p. 225), it has been felt that polypropylene side bars provided inadequate medial-lateral knee-joint support.

Another shortcoming was that, during ambulation, the calf and thigh cuffs slipped slightly up and down the patients' legs: this was due to the fact that the orthotic knee joint did not match the position of the anatomical knee joint. Although the knee orthoses were fabricated to fit closely to the knee, patients misjudged the placement of the joint when donning the device.

To improve fitting and joint placement, a new polypropylene orthosis has been designed and fabricated using a double-axis knee joint with a sliding action limited by two stops. This joint's movement closely resembles anatomical knee movements. The mechanical joint allows movement of the anatomical knee and does not cause up-and-down motions of the calf and thigh cuffs.

Fabrication was similar to that used for the previous orthosis (BPR 10-23, p. 225) except for two drape moldings; no joints were added. An aluminum disc was added between the moldings to provide a flat surface to construct the new joint. And the cast was modified in a manner similar to that of the previous orthosis, except for a build-up at the joint center. This build-up provided an area in which to construct the mechanical knee joint.

Although the new orthosis weighs only 63 grams more (approx. 2.25 oz more) than the older orthosis, it provides a better fit and better appearance. The device is currently being clinically evaluated.

2. *Orthotic Transverse Rotator.* Evaluation has been completed on the transverse rotator for lower-limb orthoses (BPR 10-28, p. 96). Four lower-limb orthosis wearers have used the device both indoors and outdoors for 3 to 6 months.

All patients have agreed that the shoe sole device functioned well. No major improvements in their gaits were noticeable, but they appreciated the additional freedom the rotator allowed them during ambulation. They were especially pleased with the ability to turn on the braced limb: this has not been possible without the rotator.

In limited indoor walking, the device proved fairly durable, but quickly malfunctioned when used outdoors—the rubber cover wore off or came off for all patients, and enough dirt then collected around the device to prevent it from rotating.

The evaluation confirms the theory that the addition of a transverse rotator to the sole of the shoe of a lower-limb-orthosis wearer is beneficial to the patient. But the present device is durable enough only for indoor use, and requires redesigning if it is to be suitable for outdoor activities.

C. Spinal-Cord-Injury Rehabilitation

1. *Environmental Control Systems*

a. *Stanley Silent Swing Door Operator.* The Stanley Silent Swing Door Operator (Fig. 1) is supplied by the Stanley Works Tool and Door Co., Farmington, Connecticut, and the Prentke Romich Co., Shreve, Ohio.

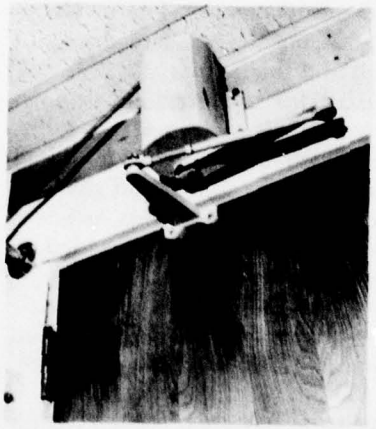

FIGURE 1.—Stanley Silent Swing Door Operator.

This electromechanical device for the home-living disabled can be mounted on a door transom to operate a light-duty interior swing-door. The door must be butt hung or swing-clear-hinge hung, with

maximum width of 42 in. (106.68 cm) and 50-lb (68.04 kg) maximum weight. A stallable, slow-speed, rotary-field drive motor, employing a built-in gear box with a 160-deg non-adjustable spindle output, is used. Two internal resilient stops stall the motor; no limit switches or return springs are used, and the motor remains energized in the open and closed positions. Although the closing motor windings remain energized, the door can be manually opened against the closing motor torque. The number of pounds of force, initial force and continuous force, required to open the door against the closing motor torque, depends upon the distance between the door hinge and the applied force.

Two Silent Swing Door Operators were submitted for evaluation. They will undergo tests in controlled conditions, and will then be installed in the homes of two disabled veterans for clinical trials.

2. *Communications Aids*

a. *Saltus Reading System.* The Saltus Reading System (Fig. 2), previously identified as the Ealing Reader (BPR 10-27, pp. 102-104), is a portable reading-assist machine intended for the severely paralyzed. Manufactured by the Ealing Corp., South Natick, Mass., the device incorporates a spool of sleeve-insert tape with clear plastic window pockets which accept pages from magazines or books. These can then be viewed. The reader can be clamped on the over-the-bed table included in the package, or on any table.

Several prototypes were evaluated for safety, effectiveness, and usefulness. Engineering tests and clinical trials were conducted in three VA hospitals and an outpatient's home.

Several modifications were instituted by the manufacturer after the device was evaluated. These are as follows:

1. Each plastic scroll pocket is split lengthwise to make it easier to insert reading material when the spool is in motion, without removing the cassette from the main frame.

2. The battery can now be charged while the unit is being operated from a 115-V a.c. source.

3. The original hand switch was replaced by several additional switch controls:

(a) Mouth Switch—Sensitive switches at the top and bottom of the mouth switch can easily be touched by the tongue, lips, or chin. Touching the bottom of the mouth switch causes the reading material to move forward; touching the top produces a reverse movement. The mouth switch attaches to a gooseneck on the device.

(b) Built-in Hand Switch—A hand switch on the upper center portion of the recessed control panel moves the material

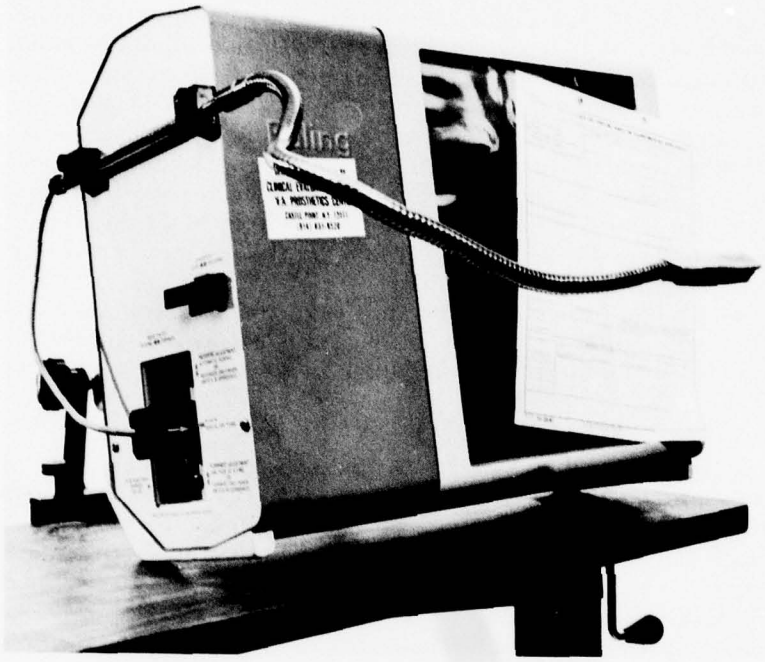

FIGURE 2.—Saltus Reading System. Lengthwise split in the transparent scroll pocket makes it easier to insert reading material.

forward and backward.

(c) Forward Adjustment Double-Throw Switch—A switch on the lower right-hand corner of the recessed control panel operates the spool either one page at a time or continuously while the switch is depressed.

(d) Reverse Adjustment Double-Throw Switch—A switch in the upper right-hand corner of the recessed control panel either automatically rewinds one page at a time or continuously while the switch is depressed.

4. The Saltus Reading System is now available in blue, yellow, green or rust.

The changes made in the Saltus Reading System should reduce loading time considerably, and its optional mouth switch should be

of practical value for independent use by high-level quadriplegics.

The Saltus Reading System is mechanically and electrically safe. It offers those with upper-limb paralysis a degree of reading independence. Its advantages over some page-turning devices are that it operates reliably once it is set up, and it can be easily adapted to various user controls, including interfacing with an environmental control system.

These advantages are achieved at the expense of considerable loading time and the necessity to purchase publications in duplicate. It is therefore recommended that the device be approved for general use by interested veterans and institutions where its advantages as well as its disadvantages are recognized.

3. *Mobility Aids*

a. *Freewheeler Power Wheelchair.* The Freewheeler Power Wheelchair (Fig. 3), manufactured and marketed by the American Stair-Glide Corp., Grandview, Missouri, (BPR 10-26, pp. 228-229) is a portable, lightweight, aluminum, power wheelchair for paraplegics and low-level-injury quadriplegics.

One unit was evaluated for safety, effectiveness, and usefulness. Engineering tests and clinical trials were conducted at two VA hospitals. The Freewheeler Power Wheelchair was unstable outdoors (on some level surfaces as well as on inclines) and it failed to meet proposed VA safety, dimension, and operation standards for wheelchairs.

b. *Electronic Power Conversion Kit For Wheelchairs.* The Electronic Power Conversion Kit for Wheelchairs (Fig. 4 and 5) can convert most American manual wheelchair models to electrically powered wheelchairs (BPR 10-26, p. 246, and BPR 10-28, p. 102). The device is manufactured and marketed by Solo Products, West Sacramento, California. It consists of left-side and right-side drive assemblies, battery case with attached electronics compartment, hand-operated proportional-control joystick on an adjustable bracket, and battery charger.

One Mark II model was evaluated for safety, effectiveness, and utility as an add-on system to power manual wheelchairs. During the evaluation, the charging circuitry malfunctioned and the company replaced the original Mark II model with their Mark III model. Both models underwent performance tests, and clinical trials of both models were conducted at the VA Hospital, Castle Point, New York, and in the home of an outpatient. While the power package performed adequately, the joystick control was jerky during high-speed acceleration and the dynamic braking of the

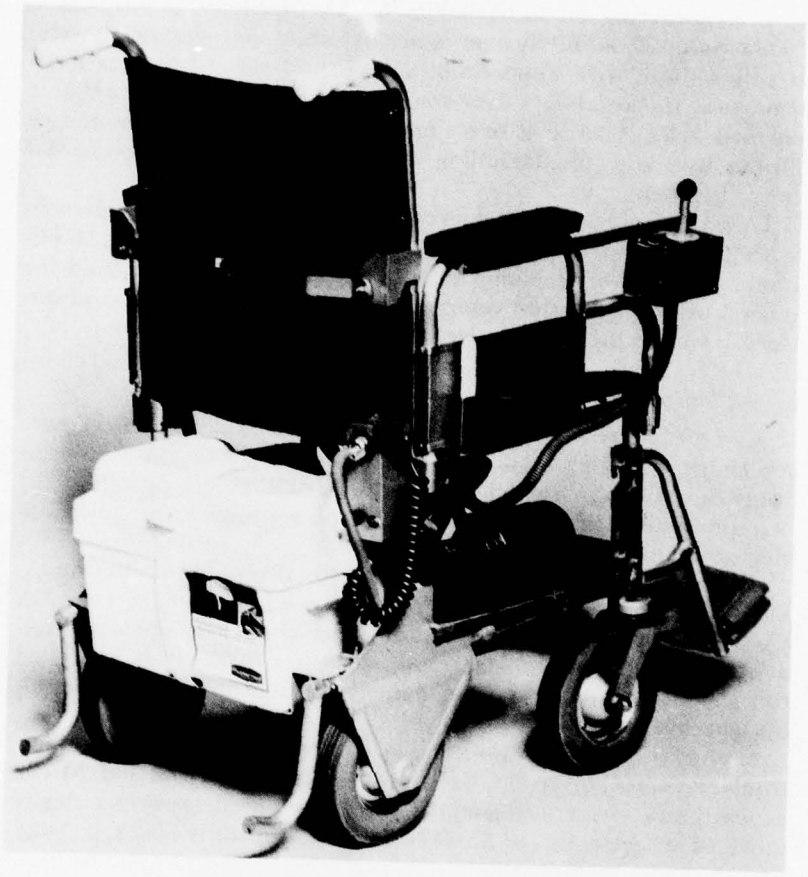

FIGURE 3.—Freewheeler power wheelchair.

drive system caused the chair to stop abruptly.

The device was returned to the manufacturer for modifications.

c. *Electric Back-Recliner Kit.* The Electric Back-Recliner Kit (Fig. 6 and 7), manufactured and marketed by General Teleoperators, Inc., Downey, California, converts all electrically powered wheelchairs with semi-reclining backs. After conversion the chair has an electrically powered full-reclining back (BPR 10-28, p. 103).

Two units were evaluated: one by the Dental Service at the Castle Point, New York, VA Hospital and one by a quadriplegic with a disability level of C4,5 who needed the reclining features of a wheelchair to relieve pressure under the buttocks.

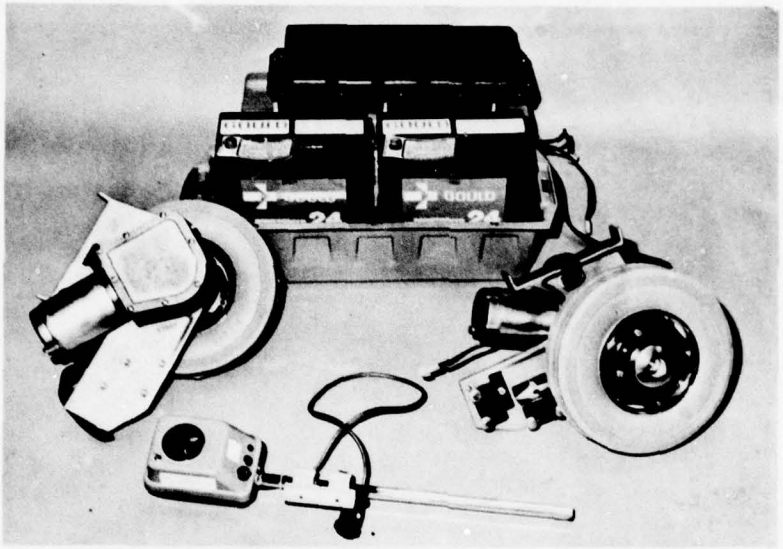

FIGURE 4.—Electronic Power Conversion Kit for wheelchairs.

Both units performed unsatisfactorily. While the back of the wheelchair reclined, the legs remained unraised, thereby producing poor posture. In addition, the control switch for activating the reclining process was overly sensitive, with the result that any degree of carelessness by the user in manipulating the switch caused the recliner back to move in the opposite direction from that desired. This makes it extremely difficult for most quadriplegics to operate the control independently and requires that an attendant be on hand to effect reclining. The Electric Back-Recliner is therefore not recommended for veteran beneficiaries.

d. *Icarus Easy Transfer Wheelchair Attachment.* The Icarus Easy Transfer Wheelchair Attachment (Fig. 8, 9, and 10), manufactured by Icarus Health Aids Ltd., Netanya, Israel, is a permanently attached wheelchair transfer board. The device is unique because, when mounted in its folded position (not in use), it replaces the wheelchair's skirtguard. (The skirtguard must be removed to accommodate the device.)

The device can be used on all standard wheelchairs with removable armrests *except* amputee chairs. It cannot be used on amputee chairs because the brake on the retractable unit cannot reach the wheel on an amputee wheelchair, as the wheelchair's drive wheels

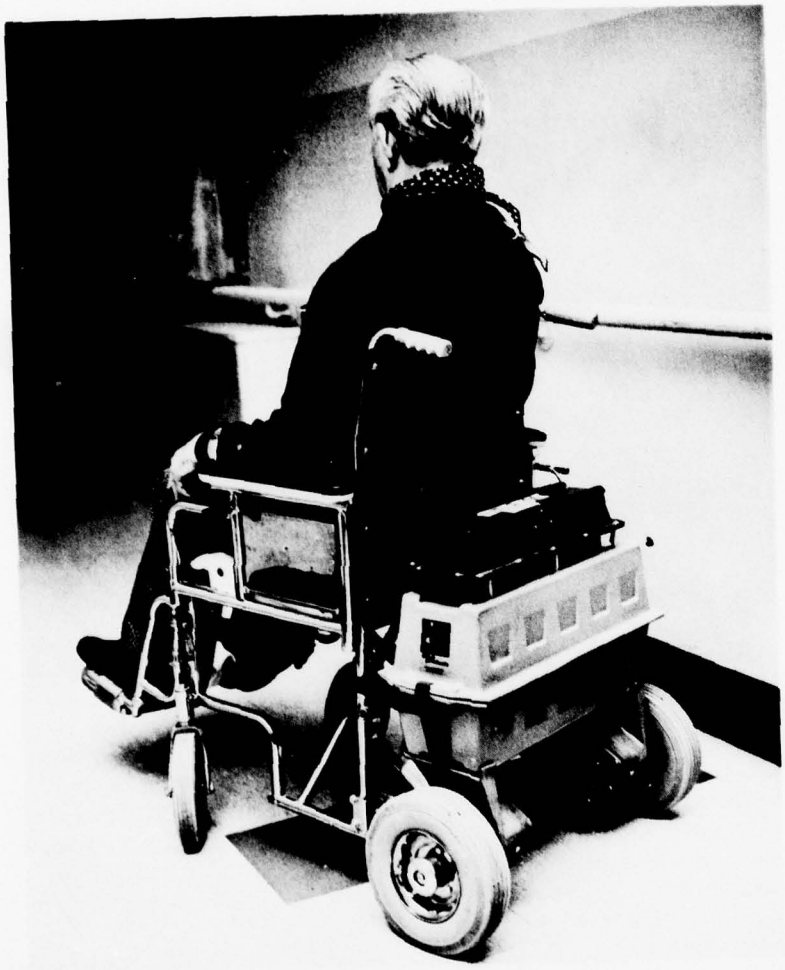

FIGURE 5. Manual wheelchair converted to electrically powered wheelchair with addition of electronic power conversion kit.

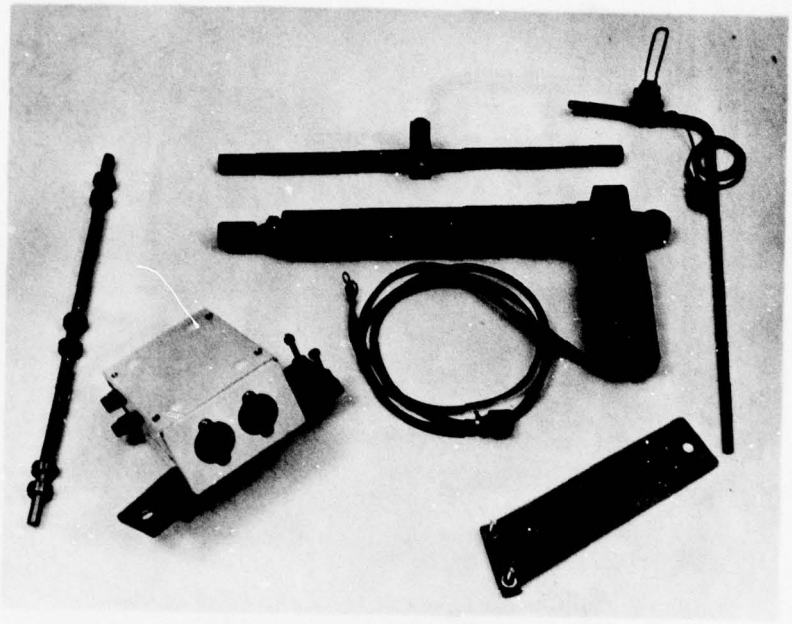

FIGURE 6.—Electric back-recliner kit components.

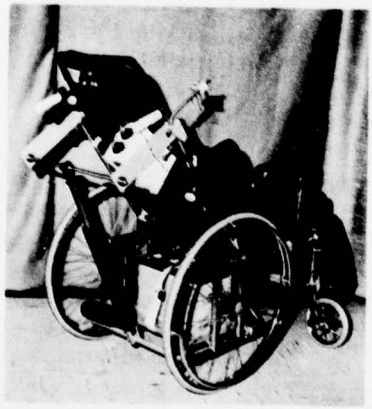

FIGURE 7.—Powered wheelchair converted to full recliner with addition of Electric Back-Recliner Kit.

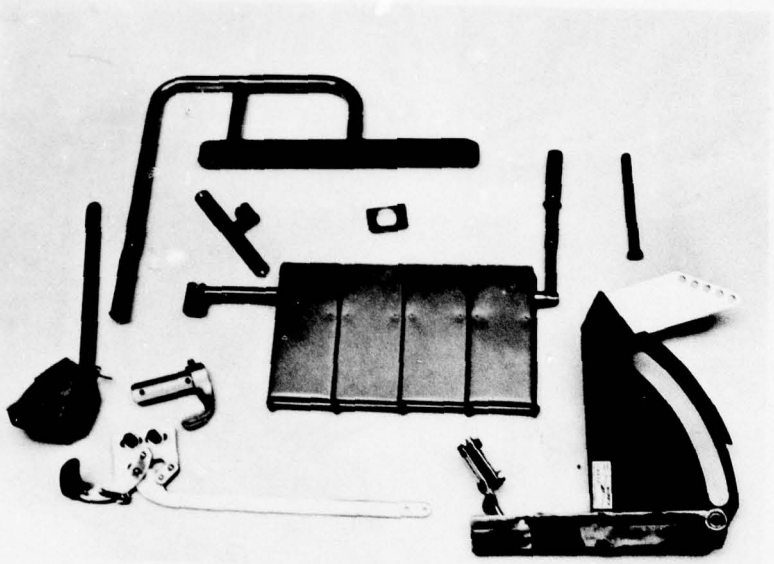

FIGURE 8.—Components of Icarus Easy Transfer Wheelchair Attachment.

are set back too far. Also if the tubular member at the lower rear frame (tipping aid) projects out by more than 4.5 in. (11.43 cm), it would require shortening, thereby permanently altering the chair.

If the user is required to transfer from his wheelchair to an automobile with the device, this can only be accomplished with extensive maneuvering.

The device is currently undergoing clinical evaluation.

e. *Arrow Wheelchair.* The Arrow Wheelchair (Fig. 11) is manufactured by the Erie City Manufacturing Co., Erie, Pennsylvania. It is an inexpensive, manually operated wheelchair. It has a chrome-plated tubular steel frame, with a double-cross flat steel brace structure that is riveted at all joints and welded to the outer tubular frame.

Two Arrow Wheelchairs (Model No. 632) were evaluated for safety, effectiveness and utility. They were checked in accordance with current "V.A. Proposed Standards for Wheelchairs, Self-Propelled, Folding, Multipurpose," and clinical trials were conducted at the VA Hospital, Castle Point, New York. They were returned to the manufacturer with recommendations for improvement.

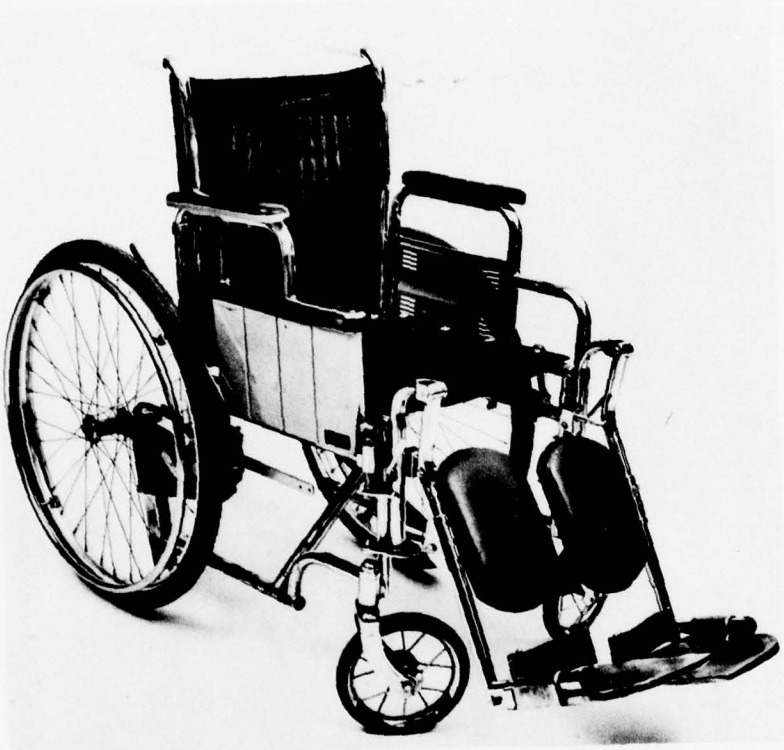

FIGURE 9.—Icarus Easy Transfer Wheelchair Attachment mounted in folded position.

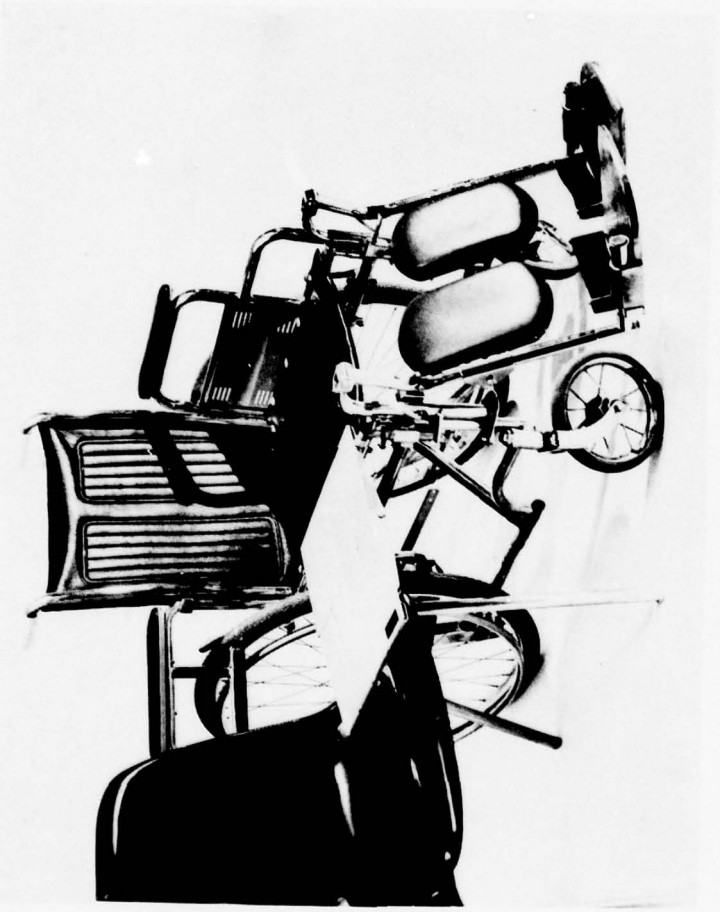

FIGURE 10.—Icarus Easy Transfer Wheelchair Attachment in transfer position.

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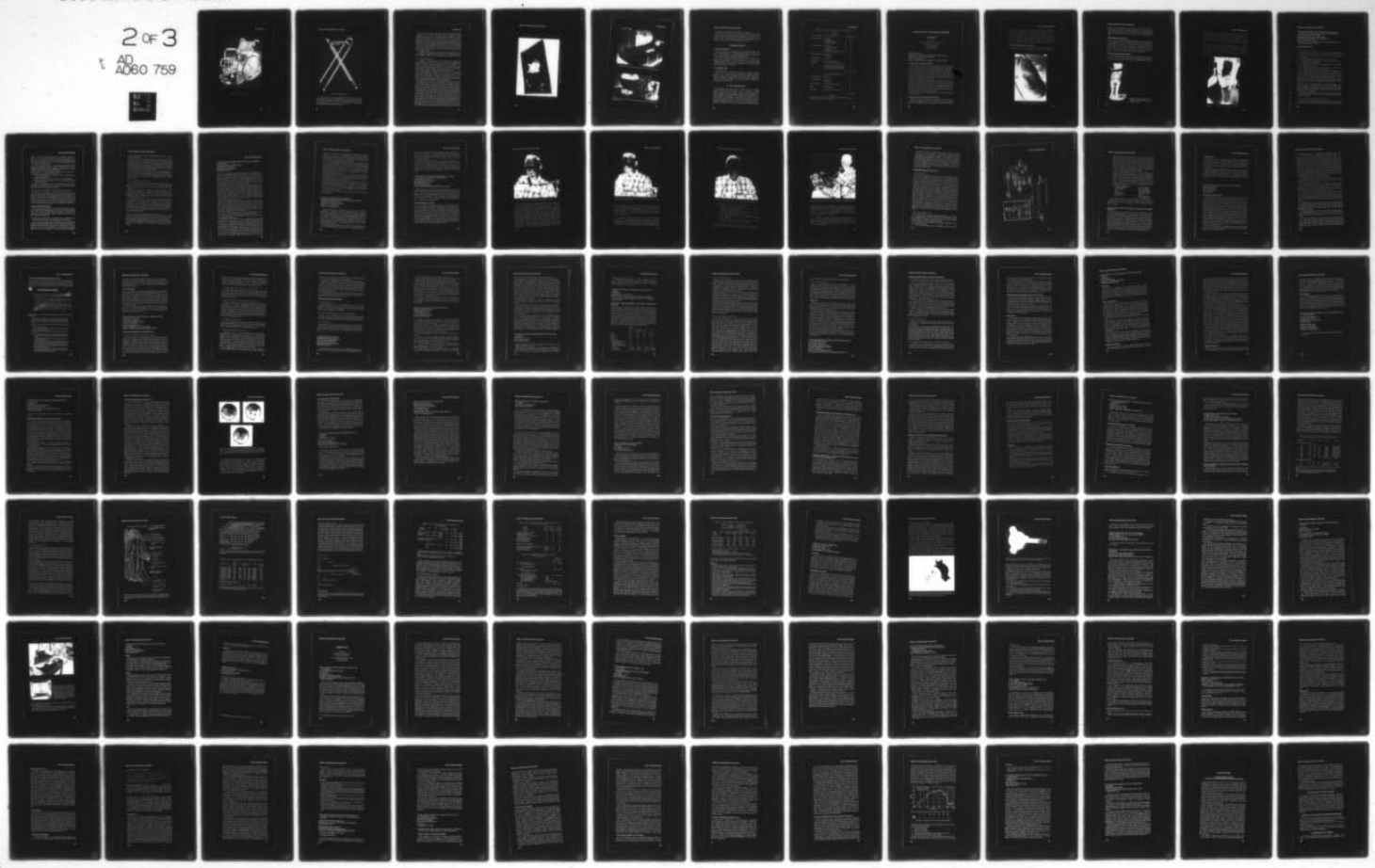

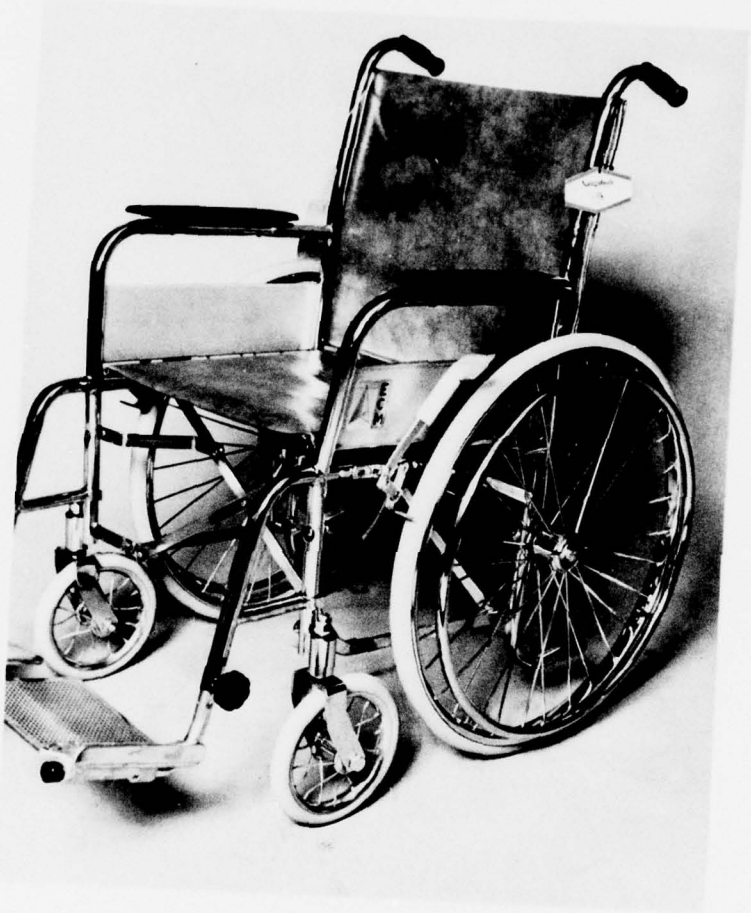

FIGURE 11.—Arrow Wheelchair.

FIGURE 12.—Rigal Walker Tray.

f. *Rigal Walker Tray*. The Rigal Walker Tray (Fig. 12) is a folding walker, much lighter in weight than conventional walkers, which can be quickly and easily folded and unfolded. It incorporates a self-contained tray. The device was submitted by its inventor, Mr. Waldo Rigal, Mount Pulaski, Illinois.

The walker underwent supervised clinical trials and laboratory compliance testing, and it did not meet acceptable standards throughout both of these tests (BPR 10-27, pp. 105-106). It was used by several patients at the Castle Point, New York, VA Hospital: these patients unanimously rejected the walker because its design prevented them from walking with proper ambulation techniques. They were required to exercise extreme care in preventing their knees or legs from hitting the device when in use, and the concept of carrying objects on the tray was far from ideal since they tended to concentrate more on the contents of the tray than on their ambulation.

In addition, the Walker Tray was subjected to laboratory tests for compliance with VA Specifications No. X-1460, dated November 27, 1967: it failed to meet specifications on a number of points.

4. *Body Support Systems*

E-Z Patient Turning System. The E-Z Patient Turning System, Model 520 (Fig. 13, 14, and 15), is commercially available from Physical Aids, Inc., El Cajon, California. It is an inflatable, two-section air mattress that is designed to turn a bedridden patient gently from a center, supine, position in the bed to a maximum angle of approximately 45 deg, to prevent decubitus ulcers.

The system employs a laminated air mattress of vinyl and nylon that is sealed down the center to create two halves. A small 20-lb (9.07 kg) air pump that plugs into a standard 110-V a.c. wall socket is used to inflate or deflate the air mattress: each half of the mattress is independently inflated or deflated. The pump shuts off automatically when the mattress is fully inflated.

The device was evaluated in the Spinal Cord Injury (SCI) Service at the Castle Point, New York, VA Hospital. The patient, who was obese, was uncomfortable when the mattress was inflated because his area for movement was limited. In addition, the mattress, which is covered with a heavy material, prevented the air from circulating under the patient, causing him to sweat and develop a skin abrasion.

The device was then evaluated by the VA Hospital, Castle Point, Medical Service staff. One of two participating patients used the device for nine 24-hour days, and the other patient used it for sixty 24-hour days. While the mattress was useful and provided good support for the back, the nursing staff recommended that it should be lengthened to cover the bed completely, and that a timer be incorporated to activate the inflate-deflate cycle at set intervals. This feature would be useful when the nursing staff is busy because it would turn the patient automatically. A patient-operated control

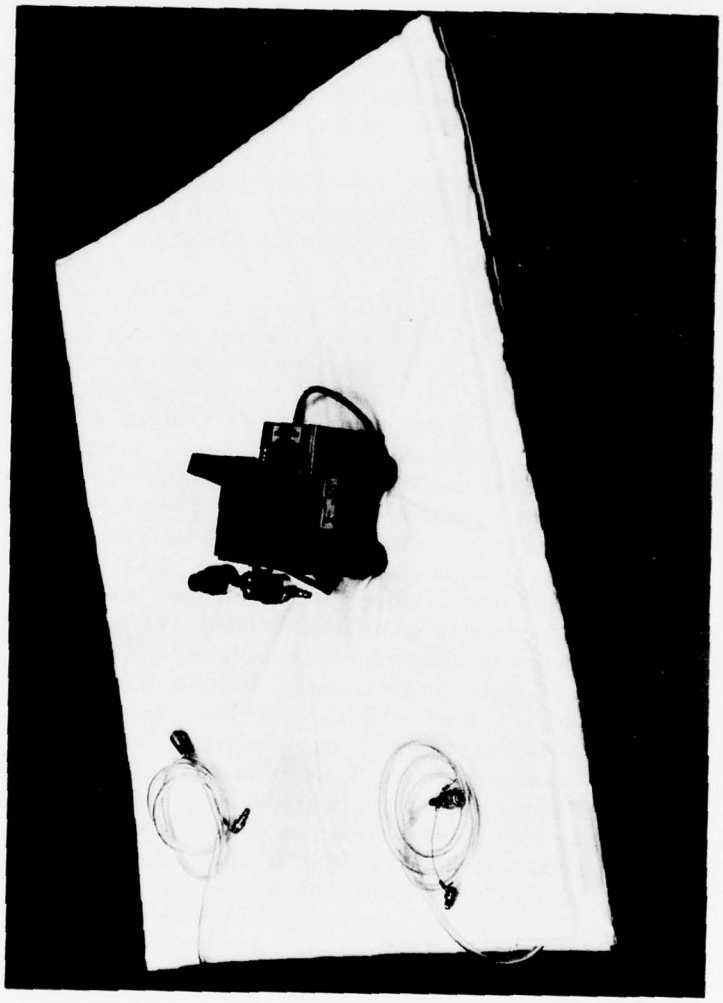

FIGURE 13.—E-Z Patient Turning System components.

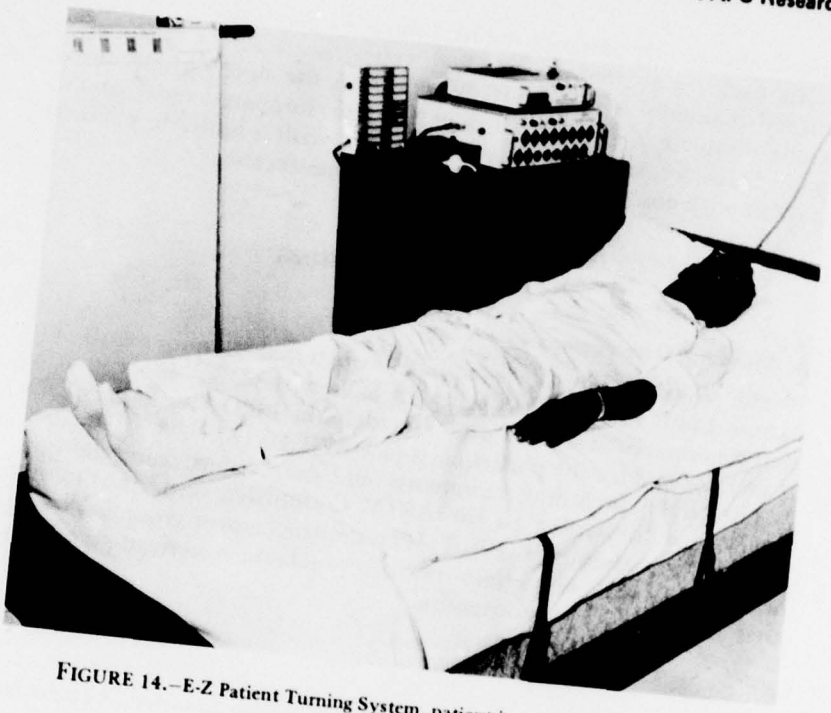

FIGURE 14.—E-Z Patient Turning System, patient in center (supine position).

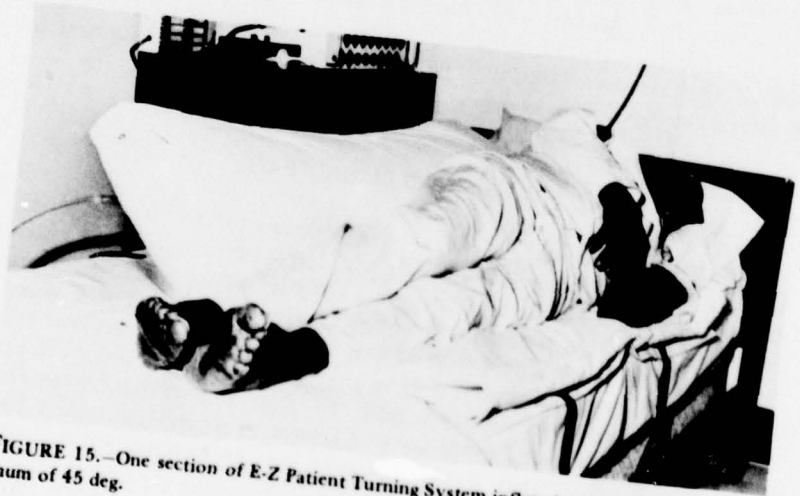

FIGURE 15.—One section of E-Z Patient Turning System inflated to turn patient to maximum of 45 deg.

would also greatly enhance the usefulness of the device.

In each case, the patient had experienced severe pain when turned manually by the staff. By contrast, the slow turning movement of the E-Z Patient Turning System eliminated most of this pain. However, when the device was tried with a multiple sclerosis patient with contractures, it proved to be ineffective.

II. COMPLIANCE TESTING

A. Standards Development

The third draft of "Standard Functional Requirements For Lower Limb Prosthetic Assemblies & Components," incorporating the recommendations of the Philadelphia ISPO Conference, has been reviewed by the participants (see BPR 10-18).

The draft, including comments and corrections from the conferees, was forwarded to the ASTM Committee on Orthotics and External Prosthetics (F-19). This committee, a peer group including VAPC personnel, was chartered to promulgate American standards that are arrived-at by consensus.

B. Compliance Testing

Corset Material

Four manufacturers submitted coutil fabric samples (3 each) for shrinkage tests: Camp International, Jackson, Michigan; Kellogg Industries, Inc., Jackson, Michigan; Medipedic Surgical Supply Co., Warrior, Alabama; and ATCO Surgical Co., Cuyahoga Falls, Ohio. All of the samples complied with the specifications contained in Solicitation No. 5244-11-78.

III. THE VAPC CLINIC TEAM

The breakdown in Table 1, of the veterans treated by the VAPC Clinic Team for the latter half of 1977, represents a typical 6-month case load that is similar to those presented in previous issues of BPR. Of the total number treated, 5 were World War I veterans, 386 were World War II veterans, 10 were Korean War veterans, 142 were Vietnam War veterans; 465 were treated for effects of service-connected injuries and 78 for non-service-connected problems. In addition, there were 5 Israeli, 1 Australian, and 1 Ex-Imperial veterans, and 2 non-veterans on an experimental basis.

TABLE 1. *Breakdown of Patient Disabilities July 1 to December 31, 1977*

Area of involvement	Specific level of involvement	Number of patients	
Amputation			
Lower-limb unilateral	Below-Knee	175	
	Above-Knee	122	
	Transmalleolar (Syme's)	3	
	Hip (Disarticulation)	7	
Lower-limb bilateral	Below-Knee	18	
	Above-Knee/Below-Knee	5	
	Above-Knee	11	
	Transmalleolar (Syme's)	2	
	Below-Knee/Transmalleolar (Syme's)	1	
Upper-limb unilateral	Below-Elbow	10	
	Above-Elbow	4	
Upper-limb bilateral	Above-Elbow	5	
Lower-limb and Upper-limb	Above-Knee/Above-Elbow	2	
	Above-Knee/Shoulder (Disarticulation)	1	
Triple	Above-Knee/Below-Knee/Below-Elbow	1	
	Above-Knee/Above-Elbow/Below-Elbow	1	
	Below-Knee/Below-Knee/Below-Elbow	1	
		369	Total
Neuromuscular or Skeletal Impairment			
Lower-limb unilateral	Ankle-Foot	111	
Lower-limb bilateral	Ankle-Foot	8	
	Knee-Ankle-Foot	10	
Upper-limb unilateral	Arm-Elbow-Forearm; Wrist-Hand	9	
Trunk	Lumbosacral spine	5	
Miscellaneous	Varied (wheelchairs, shoes, etc.)	34	
		177	Total

ERRATUM

The illustration used to depict the E-Z Way Chair Lift in BPR 10-28, p. 126, is in error. The illustration shown is that of the Compass Van.

HIGHLIGHTS OF OTHER RESEARCH PROGRAMS

PROSTHETICS

Edited by

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Synergetic Hook: Preliminary Evaluation

A preliminary small-scale clinical evaluation of the synergetic hook, conducted by the Veterans Administration Prosthetics Center and the Research Center for Prosthetics, has been completed. Although this laboratory has not received a final report, personal contact with the evaluators, patients, and prosthetists indicates that the results are generally favorable. Based on the information thus received, several changes are being made and incorporated into one hook for preliminary evaluation by this laboratory, to be followed by a more extensive clinical evaluation.

The important changes being made are: (i) reversal of slow and fast fingers, which puts the fast finger on the medial side; (ii) canting the entire hook so that the amputee can approach and grip an object in the same attitude as with a conventional hook (such as the Dorrance 5X); (iii) change to lower voltage motors to reduce the battery size; (iv) use of a current cut-off to the fast motor, to eliminate battery drain under stall conditions.

These changes are being made in addition to the changes discussed in the last report.

Powered Arm for Shoulder Disarticulation Amputees

The previous report discussed the feedback mechanism fitted to a VAPC elbow (BPR 10-28, 135). An electric wrist rotator with a similar servomechanism has been added. Sterno-clavicular position

in two planes determines the position of the elbow and wrist. Both functions are "unbeatable"; i.e., the position of the powered function cannot change without a corresponding change in sternoclavicular position. At present the prosthesis mock-up is mounted to a bench, giving the prosthesis and operator different bases of reference, inhibiting a true feeling of feedback. A socket-like device is being constructed to allow laboratory personnel to evaluate the system under conditions more equal to actual use by an amputee.

Below-Elbow Myoelectric Fitting Technique

The Alginate Impression Technique for below-elbow amputation was presented at the 1977 AOPA National Assembly, San Francisco,

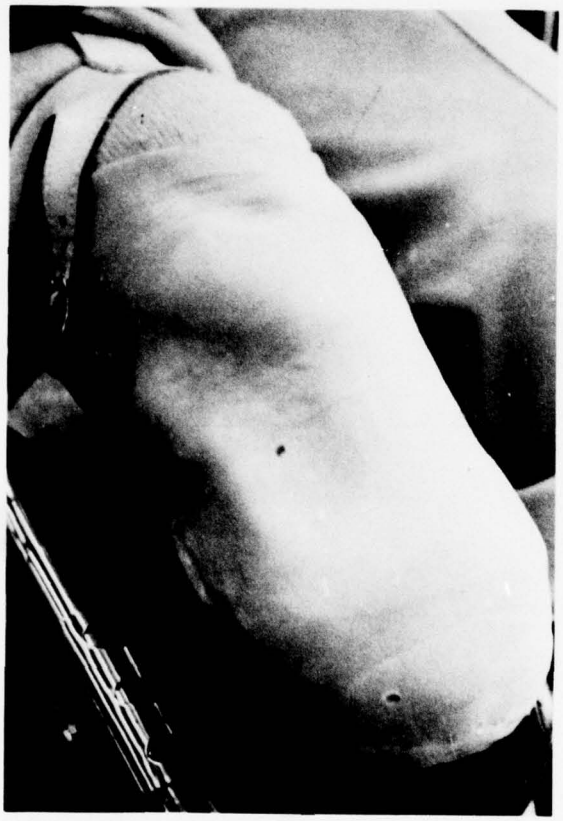

FIGURE 1.—Aquaplast inner socket

California. The technique has been modified to accommodate the proximal motion of the soft tissues when the prosthesis is donned. This is done by pulling two layers of tube gauze over the limb and applying a proximal force to the gauze before the impression is taken.

Lightweight Below-Knee Prostheses

Work on the lightweight polypropylene prosthesis design has been completed. In November 1977, this laboratory in cooperation with the Midwest Chapter of the American Academy of Orthotists and Prosthetists, sponsored a workshop on the fabrication and fitting of the prosthesis. The workshop was attended by 12 prosthetists from the private sector. The attendees fabricated six lightweight prostheses, four of which were fitted to amputees.

Temporary Thermoplastic B/K Prostheses

A temporary prosthesis for below-knee amputees is being investigated. It consists of a low-temperature thermoplastic inner socket of Aquaplast (Fig. 1) and an outer socket of polypropylene which is

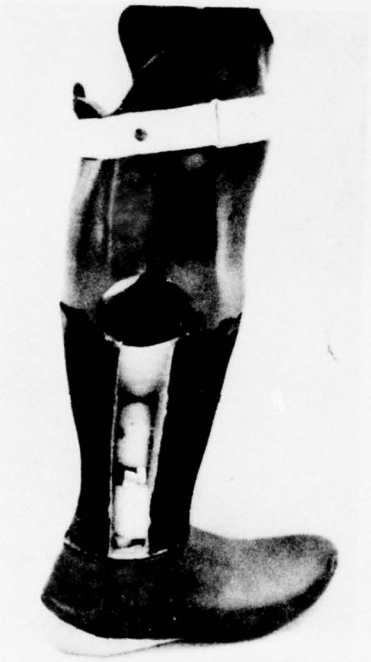

FIGURE 2.—Polypropylene outer socket and PVC (polyvinyl chloride) pylon attached to the foot.

attached to the foot by a PVC (polyvinyl chloride) pylon (Fig. 2). The Aquaplast socket can be formed directly over the limb or over a modified cast. (If applied directly to the limb some protection from the heat must be used such as cast socks.) Volume changes can be accommodated by localized heating and reshaping. The inner socket may also be worn instead of an elastic bandage or shrinker sock.

One patient has been fitted using this technique (Fig. 3). After 6 months of wearing the prosthesis, the limb has stabilized and has decreased in circumference distally by 6 cm. The inner socket was adjusted four times during that period. The results of this fitting are encouraging. The investigation will be expanded to include more amputees.

FIGURE 3.—Amputee donning outer portion of temporary prosthesis.

Fundamental and Applied Research Related to the Design and Development of Upper-Limb Externally Powered Prostheses

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Neurophysiological Studies

Electrotactile Sensory Aids

The objective of this project is to develop a general clinical applications methodology for electrotactile sensory aids for amputees using limb prostheses, and for the blind, the deaf, and spinal-cord-injured patients.

The project has been conducted in three parallel routes:

1. Collection of basic data on the response of cutaneous receptors to simultaneous multi-stimuli;
2. Development of optimal multichannel electrotactile displays based on the basic data; and
3. Development of application specifications for several sensory aids for amputees, and for blind and deaf patients.

The two-point-discrimination theory has been developed as a design concept for tactile sensory aid displays. The TPDT (two-point-discrimination threshold), as a function of body site, laterality, frequency, stimulation codes, stimulus pulse width and pulse time delay, has been experimentally defined. The effect of the TPDT variations in long and short time periods, TPDT hysteresis for ascending and descending thresholds, and electrode size, are being investigated.

Three classes of optimal displays have been developed: space-optimal, frequency optimal, and space-frequency optimal. Additional upgrading of the display types is being done concurrently with the additional data obtained regarding the TPDT response as a function of several variables.

Application of the TPDT data and theory is currently directed toward several sensory aids in the tactile, kinesthetic, visual, and auditory categories.

Functional Neuromuscular Stimulation of Limbs

A new project has been initiated in collaboration with Dr. Moshe Solomonow of the UCLA Biotechnology Laboratory, Dr. John

Foster of the VA Hospital, Brentwood, California, and Dr. E. Eldred of the UCLA Brain Research Institute. The program objectives are to develop an advanced functional neuromuscular stimulation (FNS) technique, with a goal toward allowing proportional control of paralyzed muscles.

A control scheme utilizing a proximal supramaximal driving stimulus at 60 pps (60 Hz) in conjunction with simultaneous distal partial block stimulus at 600 pps (600 Hz), both placed on a mixed peripheral nerve, is being tested for feasibility.

Data to date have demonstrated that three control variables have potential for proportional muscle contraction:

1. Block pulse-amplitude variations of the subthreshold to suprathreshold range;
2. Block pulse-width variations in the range of 10 μs-500 μs;
3. Block frequency variations in the range 100 pps-1000 pps (100 Hz-1000 Hz).

Efforts are currently directed toward quantification of the data and definition of optimal block parameters for maximal dynamic range of proportional muscular contraction.

Upper-Limb Prosthesis Project Using Microprocessor Hardware

All subsystems, including the prosthesis structure, the control circuitry, belt-mounted microprocessor, myoelectric amplifiers, and ADC were built, tested, and debugged. The pattern recognition software was also tested, on the portable system, and is ready to be evaluated. Current efforts are directed toward the selection of several amputee subjects, to cooperate in the clinical evaluation and system integration program planned for the remainder of this year.

Evaluation of Medical Manipulators

The Biotechnology Laboratory at UCLA has continued to implement its three-stage evaluation protocol on remote medical manipulators. This report will summarize the progress throughout the evaluation of the manipulator systems which were received from the Veterans Administration.

1. Rancho Los Amigos Remote Manipulator No. 12 (Golden Arm) Articulated Seven-Degrees-of-Freedom Remote Manipulator

After a full bench-testing phase, the Golden Arm was introduced into our clinical evaluation stage at the VA Hospital, Long Beach, California. The parameters of interest were patient speed, accuracy, functional range, control modality, and subjective acceptance. Objective tests were designed to assess the patient/manipulator

system in these areas, which require learning and practice in activities of daily living.

In summary, the results indicate faster learning speed, in performance tests, with a proportional-control method. However, patients using the "bang bang" switch control establish a learning plateau, after time, at about the same performance level as patients using the proportional control (about 1.5 min/high accuracy movement). The implication is that this plateau reflects a system limitation rather than a patient performance limit.

Unobtrusive long-term monitoring with a Swedish HMS microcounter system has been instituted, and patient use will be monitored and recorded. This record will be maintained after the patient leaves the clinic, as an indicator of manipulator utility in a daily-living situation.

2. Telescoping Manipulator Models

Two telescoping models were evaluated through the bench test phase of our evaluation. One was voice controlled (the Santa Barbara Voice Control System); the other was proportional joystick controlled.

Before they would be suitable for clinical evaluation, both telescoping manipulators were found to need major modification in damping, telescope extension and retraction, and in the prehension subsystem. These modifications are currently being effected by General Teleoperators, Inc.

The Santa Barbara Voice Control System was tested for percent recognition rate and to determine if there was any effect on that recognition rate by the order and combination of the command words used (co-articulation effect). In summary, the results indicate that with use of the retraining feature, the 10 word vocabulary of the system could be processed at above a 90 percent recognition rate. There were no significant co-articulation effects in the two-word command sequences.

3. The Johns Hopkins Manipulator-plus-Worktable System. This system was being bench-tested when an electrical problem developed in the control circuitry. The problem was corrected by the Johns Hopkins Applied Physics Laboratory, and bench-testing of the system has resumed. Following completion of the engineering evaluation, the manipulator system will be evaluated in a clinical setting.

Control of an Artificial Upper-Limb Prosthesis in Several Degrees of Freedom

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Work on the multifunctional above-elbow prosthesis, during the report's 6-month period (July 1, 1977-Dec. 31, 1977), has been spent on preparing a number of demonstrations of the system to VA-arranged site visitors. We were asked to demonstrate that we are able to discriminate among several limb functions from a single muscle signal site. This has been successfully demonstrated and reports from the site visits testify clearly to this.

It appeared that there was difficulty in understanding the concept that cross-talk between two muscles could be used (rather than being filtered out) if surface electrodes were located between two muscles (such as between the biceps and triceps muscles) so as to maximize cross-talk. By processing the complete information in such a signal, through modern time series analysis techniques and using microprocessor hardware, we can accomplish the discrimination described, such that several limb functions can be reliably actuated from a single signal source.

The understanding of this concept is analogous to that of the problem of discrimination between "Yes" and "No" when it is well known that the level of speech in pronouncing the words cannot, alone, yield discrimination between the two words. It was as if we were looking at all parameters of the time series of the signals "Yes" and "No", rather than at the level (speech power) of these words, such that discrimination becomes possible.

We differ considerably (and not at all surprisingly) from investigators accustomed to considering signal level (power) alone.

Our demonstrations were all based on using a real time microprocessor (Intel 8080) system.

In addition to the "mere" ability to discriminate between limb functions from a single signal site, we have found and demonstrated that the time series parameters are almost independent of the level of actuation, to indicate the feasibility of employing signal level for proportional speed/torque control. Also, we have shown that parameter values were repeatable within a very few percent from visit to visit (over several months), even though the electrode location varied at ±0.5 cm. Furthermore, we have shown in these demonstrations that, on non-amputees, parameters for a given electrode location and for a given limb function varied only by a few percent

from person to person, again with locations wtihin 0.5 cm. at best. The latter result points to the possiblity of using our approach also for diagnosing muscular and neural disorders in amputees and in non-amputees, the diagnosis being dependent on establishing a library of parameter values per given disorder.

All of the capabilities demonstrated and the possibilities indicated here require clinical testing. We have established cooperation with John Boswick, M.D., of the University of Colorado Medical School, Colorado General Hospital, in Denver, Colorado, and the VA Hospital, Denver. We are, therefore, very hopeful that with the vast clinical experience of Dr. Boswick, meaningful clinical tests will be possible in the near future.

During the period of this report, a second patent application has been prepared on the above work, in addition to the recently awarded US Patent No. 4, 030,141 by D. Graupe. The latter patent has been filed in several foreign countries.

Finally, several papers on this work have appeared or have been accepted for publication, during this six-month period, to bring the total number of publications on this project to 13, excluding reports and guest lectures, and also excluding several discussions of this work in surveys and review papers published by workers who are not members of this group.

A report of a Peer Review has been submitted to the VA during the same period.

Position Control of Above-Elbow Prostheses

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Lawrence E. Carlson, Ph. D.

The upper limb can be thought of as having two functional components: a grasping device (the hand) and a means to position the hand in space. Direct position control offers many advantages for controlling the latter task. Extended physiological proprioception (EPP), as developed in Scotland by David Simpson, has proved to be a very successful implementation of position control. Unfortunately, his system controls pneumatic prostheses as fitted in the United Kingdom, which are incompatible with the electric systems as fitted in this country.

The basic principle of EPP is to use relative body displacement to control prosthesis displacement directly. A mechanical feedback

link from the prosthetic joint to the input transducer links the input to the output, thus extending the body's proprioception into the prosthesis. Control of a prosthesis is therefore very much like conventional cable control but with greatly reduced force and excursion requirements.

The goal of this research project is to develop an EPP system for controlling a VA electric elbow with a minimum of modification. The project will include design and evaluation of the various components of the system, prototype testing on normal subjects, and evaluation of a refined system by amputees. In addition, studies will be performed to evaluate the suitability of various control sites for EPP.

Interdisciplinary Development and Evaluation of Externally Powered Upper-Limb Prostheses and Orthoses
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Laurel, Maryland 20810
Woodrow Seamone and Gerhard Schmeisser, Jr., M.D.

The primary activity during the latter half of 1977 was the continued development and evaluation of the powered medical manipulator system for the high-level spinal cord injured person. This project has focused on techniques which offer increased self-capability, along with mobility, for the quadriplegic. Three months of clinical evaluation of the computer-aided powered manipulator were conducted during this period.

Dual-Purpose Wheelchair Controller

A new dual-purpose controller has been designed for an electric wheelchair. This device allows the quadriplegic to retain the mobility of an electric wheelchair in conjunction with the ability to operate the JHU powered medical manipulator/worktable system. The selection and control of either mode is accomplished without assistance from an attendant. Figure 4 illustrates a conventional chin-operated wheelchair controller. Although this controller provides good controllability, its size and location in front of the face are undesirable attributes of this system; a patient in such a wheelchair has mobility but cannot perform functions without help from an attendant after reaching a particular location.

FIGURE 4. Conventional chin-operated electric wheelchair.

This same electric wheelchair (Invacare Model with Kollmorgen Drive) is illustrated in Figure 5 with new design features as follows:

1. A low-profile two-axis chin controller replaces the original joystick controller. Power to the wheelchair motors is applied by depressing the chin lever downward. Steering is accomplished by swinging the controller left or right. Thus, proportional control attained is similar to that attained with the original joystick. A main power relay was added. It remains in the off position until activated by the initial downward motion of the controller. A microswitch, integral on the chin piece, allows selection of reverse mode when the controller is in the upward or relaxed position. This arrangement results in an easy-to-control system. Figure 5 shows the chin controller in its normal wheelchair driving position. An important change in this system, compared with the original controller, is the

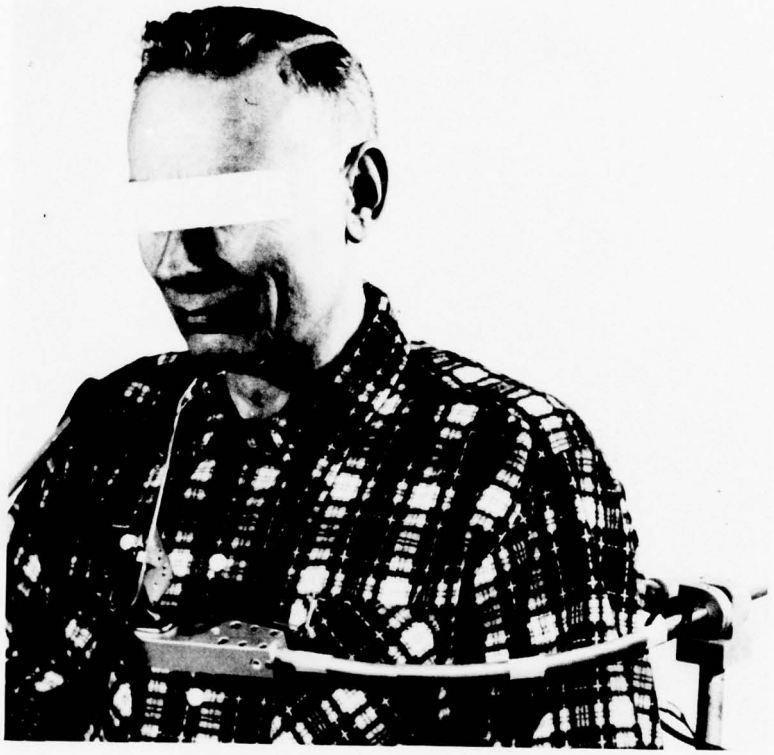

FIGURE 5. Dual-purpose wheelchair controller provides control of wheelchair and powered medical manipulator/table.

lack of spring-force-centering in the lateral axis. This feature allows the user to push the chin controller off to the side, it then remains out of the way of his face during periods of non-use: this mode is illustrated in Figure 6. (A slight mechanical detent is provided to allow the operator to feel the straight-ahead position of the controller, when steering.)

2. Since the low-profile controller moves the control equipment away from the area directly in front of the mouth, a two-piece mouthstick in a holder (previously located on the JHU manipulator worktable) may now be located on the wheelchair lap board. This two-length mouthstick is available for use by the quadriplegic with-

FIGURE 6. Wheelchair controller swung away from operating position by user.

out attendant assistance, to carry out tasks such as:

a. turning pages of a magazine or book;
b. operating easy-touch electrical switches on any wall within range of the wheelchair;
c. operating standard keyboard devices such as electric typewriters and computer terminals;
d. direct operation of channel select, volume controls and on-off switch for some TV sets such as the Sony push-button model; and
e. pushbutton operation of conventional telephones with the handset suitably mounted on a wall bracket.

3. This wheelchair lap board also incorporates a fold-down Lucite magazine/book reading stand with wire page-retaining fingers

FIGURE 7. Wheelchair reading rack with page-holding wire fingers. Mouthstick is used for turning pages.

to allow the user to do his reading in a location of his choosing. Reading using the wheelchair's reading stand is illustrated in Figure 7. The mouthstick is used for page turning and adjusting the wire fingers to retain the pages of paperbacks. As an alternative, he would have the option of sitting in front of a table with books arranged on a plywood reading stand.

4. An optical coupling (not shown in the illustrations) is provided to allow use of the same wheelchair chin controller to operate the powered manipulator when the wheelchair is suitably located in front of the manipulator table. (The details of this interface are described later in this progress report.)

The wheelchair control configuration shown in Figures 5, 6, and 7 provides good controllability of wheelchair mobility in addition to allowing an expanded degree of usage for the mouthstick. This is accomplished with minimum addition of components over the existing electric wheelchair system. One Invacare electric wheelchair has been modified with the above features and successful testing has been accomplished in the Laboratory. Arrangements are now being planned to conduct clinical testing with a quadriplegic volunteer, to get additional data relative to this wheelchair control concept in an actual user environment.

Powered Manipulator Design Improvements

1. Optical Coupler

The chin controller (now located on the wheelchair) must of course also be capable of operating the powered medical manipulator on its worktable. This control function is accomplished by providing an optical signal-coupler between the wheelchair and the worktable. The dc or proportional signal of the chin-control potentiometer is changed to FM, transmitted via an optical link to the table and converted back to dc. This is accomplished by using a low-cost integrated circuit. The Teledyne 9400 voltage-to-frequency converter ($14.00) is used in this application. The pulse input from the microswitch on the chin controller is transmitted by blanking the FM signal and detected by a zero-voltage detector circuit. This optical coupling is designed to function when the wheelchair is driven to a location within ±2 cm of a designed alignment position on the manipulator table. Lifting up momentarily on the chin controller transfers control from the wheelchair motor signal path to the optical path, thereby allowing the user to select either wheelchair mobility or manipulator control. This is accomplished without assistance from an attendant. Laboratory demonstrations with the modified electric wheelchair have verified that this optical coupling alignment is non-critical, and the signal to the manipulator is noise-free.

2. Mode Select/Program Select

The Applied Physics Laboratory/JHU manipulator is controlled via a microprocessor, as indicated in Figure 8. This earlier system used a time scan sequence for function mode select and a two-digit numeric display for the automated programs.

Two changes are being explored to simplify the interface command. These changes are:

a. The display software has been modified to allow the initial

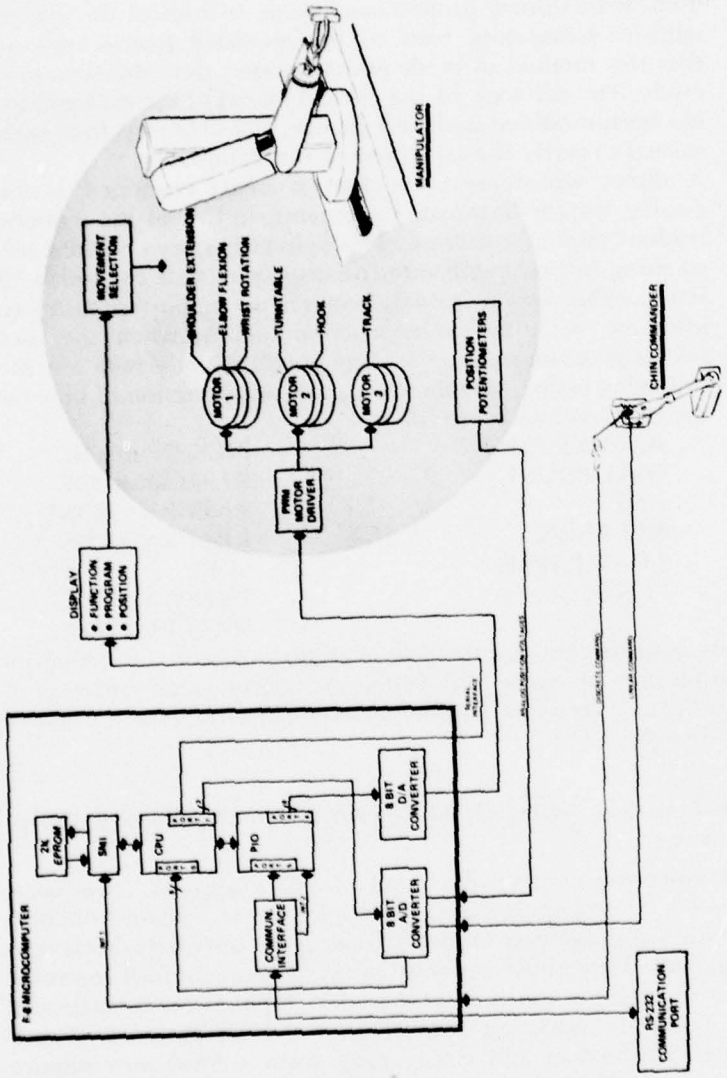

FIGURE 8.—Microcomputer-controlled manipulator.

depressing of the chin controller to call up basic operating functional modes as a function of how far the chin lever is depressed. Once the mode has been selected, the chin lever is used in its normal proportional mode to control the axis of motion. Laboratory tests of the modified system indicate that this method of mode select is easier than the time scan mode. The software of the clinical model of the manipulator has been modified with this change, and field tests have been started to verify the usefulness of the change.

b. A direct alphanumeric readout is being examined as the display for the automated programs, in lieu of the numeric readout presently utilized. This system has been breadboarded using Litronix alphanumeric display models to display 12 letters. This display module requires no support circuitry to interface with the microprocessor. Thus, when the user selects program mode, this display will directly read out the following listing, one line at a time, as a function of how far the chin lever is depressed—

ANSWER PHONE	PICK UP BOOK
DIAL PHONE	RETURN BOOK
EAT	RETURN PHONE
KLEENEX	RETURN TYPE
LOAD PAPER	SOUP
PARK	TYPEWRITTER
	WATERCOLOR

Tests indicate that this method of displaying stored program information may be easier to use than the numeric representation of each program. Tests are continuing to further refine and evaluate this technique.

Clinical Evaluation Testing of the Computer Controlled Powered Medical Manipulator

The computer controlled version of this manipulator has been undergoing clinical testing by a quadriplegic, for a 3-month period as of this reporting date. Results from these tests have been very encouraging. They show a significant system operational improvement over previous non-computer models. Input effort is materially reduced for all tasks, yet manual control intervention is always possible. Self-feeding and eating soup from a bowl now require only minimal effort. This user has further requested that the plate capacity be increased in order to make self-feeding a practical reality. A new ceramic plate has been fabricated and additional self-feeding exercises are planned to further evaluate this function.

Continuing Plans

Software and hardware design work is underway to implement the capability to program the manipulator more easily, with a functional keyboard to execute desired automated motion sequences. The software structure and electronic modifications necessary for combined multi-axis motion during program mode are being defined.

Clinical tests will be continued with the experimental system to evaluate design improvements as they evolve. One earlier model of the JHU manipulator work table system is being returned from the VA Hospital, West Roxbury, Mass., for refurbishment with the microprocessor controller and wheelchair modifications as described earlier.

Research and Development in the Field of Artificial Limbs

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Hydraulic Ankle Control System

On July 20, 1977, the foam mixing and pouring machine was received. Putting the machine into operation turned out to be more complicated than expected, due to the need for compressed air of higher than shop pressure, for nitrogen under pressure, for three-phase 220-V current, various chemicals, and the correction of several minor malfunctions. It was also found that the molds had to be pre-heated to 140 deg F in order to avoid too-heavy skin formation on the foot surface, and that the resin component of the foam had to be stirred with a motor driven stirrer, before pouring, to counteract the separation of the resin ingredients of different specific gravity. Finally, it became necessary to install under the machine a small space-heater to prevent the temperature of the isocyanate foam component from dropping below its freezing point of 50 deg F during the night and over weekends, due to energy conservation measures. (Thawing can only be accomplished by putting the entire machine into some kind of environmental chamber at 180 deg F for several hours.)

All of these problems were eventually solved and the pouring of foam feet of good quality (which had never been done here before) has now become a routine matter.

The shakedown tests of the Hydraulic Ankle, by the VA in New York and by the two test amputees in Dayton and Arizona, have been continued. They had important results leading to five minor and five major design modifications. The five minor ones included: higher basic setting of the hydraulic over-pressure valve inside the hydraulic unit; switch from Viton rubber to polyurethane rubber for the U-seals to facilitate de-molding without tearing; more clearance for the ceramic control ball inside the hydraulic unit, to prevent contact with the rear vane piston surface which had caused occasional clicking noises; slitting the ankle bolt longitudinally throughout its length to provide better holding power upon expansion, thus preventing sideward migration and piercing of the rubber boot; and keeping the dorsiflexion spring assembly from getting out of adjustment by adding a counterlocking set screw.

The five major design modifications included:

1. Redesigning of the bypass valve to prevent leaks and to avoid mechanical obstruction (by means of a larger orifice, wider overlap, and more freedom of motion);
2. Redesigning of the shaft of the foam foot, to eliminate noise caused by friction between its inside and the outside of the lower shank end (by molding onto the inside surface of the shaft two kinds of fabric, one stretchable and one non-stretchable, to provide non-rubbery surface and an adjustable elastic edge);
3. Redesigning of the bearing elements at the piston rod tip, which serve to attach it to the inside of the shank, in order to prevent clicking noises upon load reversal (because all clearances provided for adjustment purposes but not needed during actual walking are now reduced to zero by the pressure of the attachment screws);
4. Redesigning of the bearing elements at the piston rod neck to eliminate groaning noises upon weight application (through the use of special, multi-layered, Teflon based, steel jacketed bearing bushings, which will not compress under load, and thus allowing close tolerances); and
5. Reinforcing of the piston rod, one of which broke during the New York shakedown tests, to prevent fractures (by additional heat treatment for existing rods plus larger cross-sectional area in future ones).

All these improvements are having their expected beneficial effects, resulting in trouble-free operation of the three systems under test at this writing. However, only future shakedown testing with additional amputees will tell whether the necessary long range performance (at least one year of maintenance-free operation) is within reach.

Voluntarily Actuated Swing and Stance Control System

Very limited time could be devoted to the Voluntarily Actuated Swing and Stance Control System project, because of the high priority given to the Hydraulic Ankle as just described. However, some studies were undertaken with the purpose of assessing the possibili-

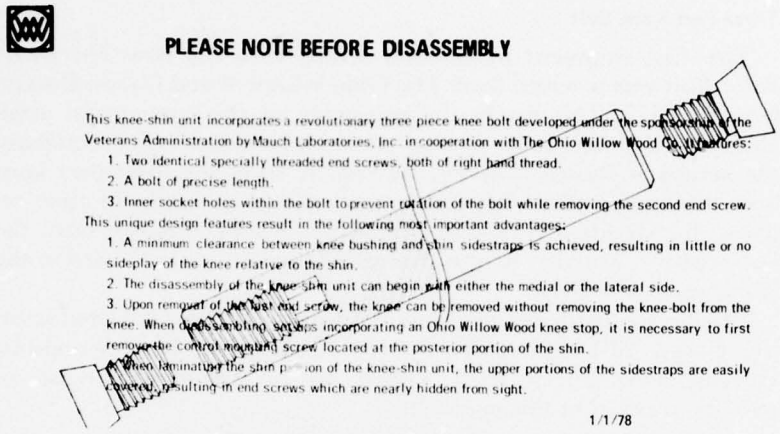

FIGURE 9.—Label on wooden setups explaining the three-part bolt. The text of the label reads as follows:

> This knee-shin unit incorporates a revolutionary three piece knee bolt developed under the sponsorship of the Veterans Administration by Mauch Laboratories, Inc., in cooperation with The Ohio Willow Wood Co. It features:
>
> 1. Two identical specially threaded end screws, both of right hand thread.
> 2. A bolt of precise length.
> 3. Inner socket holes within the bolt to prevent rotation of the bolt while removing the second end screw.
>
> This unique design feature results in the following most important advantages:
>
> 1. A minimum clearance between knee bushing and shin sidestraps is achieved, resulting in little or no sideplay of the knee relative to the shin.
> 2. The disassembly of the knee-shin unit can begin with either the medial or the lateral side.
> 3. Upon removal of the last end screw, the knee can be removed without removing the knee-bolt from the knee. When disassembling set-ups incorporating an Ohio Willow Wood knee stop, it is necessary to first remove the control mounting screw located at the posterior portion of the shin.
> 4. When laminating the shin portion of the knee-shin unit, the upper portions of the sidestraps are easily covered, resulting in end screws which are nearly hidden from sight.

ties made available by the advent of the microprocessor in the electronics field. It seems possible to widen the scope of the control functions for swing as well as stance situations in a voluntarily controlled hydraulic knee system, by utilizing this breakthrough in electronic technology.

Three-Part Knee Bolt

The first shipment of wooden setups with the new Three-Part Knee Bolt was received from The Ohio Willow Wood Co. on December 22, 1977. This marks the beginning of the commercial availability of this new bolt. A copy of the label which will accompany the setups is shown (Fig. 9). As can be seen, the three-part knee bolt has many advantages over, and will most likely in time replace, the standard A-K knee bolt which has been in use since the last century. For this reason, the word "revolutionary" used in the label may be forgiven.

The bolt is made by the Allmetal subsidiary C & A Manufacturing Corp., 24-30 Brooklyn-Queens Expressway, West Woodside, Queens, New York 11377. (There are no commercial rights or patents involved in this matter.)

Design of Prosthetic and Orthotic Devices and Biomechanical Studies of Locomotion

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James M. Morris, M.D., and Larry Lamoreux, Ph.D.

Design of Lower-Limb Prosthetic and Orthotic Devices

1. *Four-Bar-Linkage Polycentric Pneumatic Knee*

Requests for bids from the prosthetics industry on the construction of 50 complete units, including knee mechanism, spherical alignment coupling, pneumatic damper, and pylon structure with coupling for a SACH foot, were sent out by VA Prosthetics Center during this report period. Bids were received from three companies, but all three bids were rejected by the VA procurement officer in New York because of variances from the engineering drawings submitted. (One bid suggested replacement of a welded subassembly by a fully machined part, and another proposed the use of a modified commercial swing-control unit rather than a whole new unit.)

During the next report period, possibilities will be investigated for production of the units under a subcontract directly from the University of California project, in an effort to better utilize the production engineering capabilities of the prosthetics industry to achieve faster progress from prototype to production item.

2. *Six-Bar-Linkage Knee with Friction Swing Control*

This knee-disarticulation prosthesis has been revised for increased bearing strength, and a single prototype will be fabricated to the new drawings during the next report period. Cosmetic covers patterned after the new molded foam covers for the Four-Bar Knee will also be developed.

3. *Dual-Action Safety Knee (Friction-Stabilized Knee)*

A friction stabilized knee is often prescribed for amputees who need assistance in achieving reliable knee stability at heel contact. The dual-action safety knee was designed to provide knee friction at heel contact, but to release the friction at toe off, allowing easier initiation of swing phase. The same friction brake also provides an adjustable swing-phase control. A third prototype unit has been constructed and tested in the laboratory. This unit appears to satisfy all design goals. Preparation of cosmetic covers is underway to permit extended amputee trials.

4. *SACH Foot with Metal Keel*

The metal-keel SACH foot is performing well in amputee trials. Metal keels produced to date have been machined from solid aluminum. A pattern is being prepared for production of 25 or more cast aluminum keels to allow more extensive amputee trials.

5. *Multi-Input Control of Knee Stability*

A single-axis knee has been assembled that incorporates a hydraulic damper, and transducers that measure knee angle, knee angular velocity, and hip flexion/extension moment. The hydraulic damper provides swing-phase control and stance-phase control. The amount of resistance is controlled by a motor-driven rotary valve. For development of optimal control logic based on the measured variables, the laboratory minicomputer is being used as a controller. When the safest and most functional control logic has been established, a compact hybrid controller can be constructed.

Control algorithms have been developed for active swing-phase control, terminal impact detection, knee lock when going into

stance phase, and detection of voluntary knee-yielding at the end of stance phase and emergence into swing phase.

At present, it is assumed that total knee lock during mid-stance is desirable. The immediate goal is to further refine and control the knee buckling process to fully utilize the knee angular velocity control feature of the prosthesis. In addition to the normal mode of operation, a hip-moment override allows the amputee to voluntarily flex the knee when he encounters unusual situations such as descending ramps or stairs.

A special bent-knee socket has been fabricated to permit testing by normal subjects. Amputee trials will proceed when control is judged to be suitably safe and functional.

Mobility Aids for the Physically Disabled

1. *PRAHN Wheelchair*

Detail drawings for the first PRAHN II prototype are nearing completion and the fabrication of parts is under way. The first prototype is scheduled for completion by April 1978, when it will begin testing and evaluation in Berkeley.

2. *Wheelchair Spring Suspension Powering Unit (SSPU)*

Parts for the second SSPU prototype have been fabricated, and assembly is expected to be complete by March 1978. The unit will be tested in Berkeley and perhaps also at the VA Prosthetics Center.

3. *Urinal Bag Clamp*

Five urinal bag clamps are being used in Berkeley. They have performed well following some initial leakage problems caused by faulty forming of the end hooks on the springs. Five clamps were sent to the VA Prosthetics Center in September 1977 for evaluation.

Ultralight Below-Knee Prosthesis

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Moss Rehabilitation Hospital
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Philadelphia, Pennsylvania 19141
A. Bennett Wilson, Jr.

The original 6-month contract was completed April 30, 1977. A manual on the fabrication procedure for an ultralight below-knee

prosthesis and a final report were prepared for the VA.

It was recommended that the VA undertake a nationwide clinical evaluation program through their formal amputee clinic teams.

The VA requested that the Rehabilitation Engineering Center, Moss Rehabilitation Hospital, submit a proposal for a local clinical study, and a proposal was submitted in May 1977 for the conduct of such a study. This proposal was approved and contact was reestablished with the local prosthetics representative and the clinic teams serving the VA in this area. All other local prosthetics facilities certified by the American Board for Certification in Prosthetics and Orthotics were also offered an opportunity to participate. All but one facility responded positively.

A draft protocol for the clinical study was prepared and presented to prosthetists representing facilities in the area. (Two facilities were unable to attend a workshop but they agreed to participate in the study.)

Immediate Postoperative Prostheses Research Study
Prosthetics Research Study
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1102 Columbia Street
Seattle, Washington 98104
Ernest M. Burgess, M.D.

A number of clinical evaluation and research studies which have been underway for some time at PRS have, in the last few months, been finalized. The Bernice Kegel, et al., report, "A Survey of Lower-Limb Amputees: Prostheses, Phantom Sensations, and Psychosocial Aspects," appeared in BPR 10-27. A comprehensive additional survey by the same authors, relating to amputee function, has been accepted for publication and will appear in the Archives of Physical Medicine and Rehabilitation.

Accepted for publication and/or recently published are the following:

1. Prevention of Thromoboembolic Disease by External Pneumatic Compression in Patients Undergoing Total Hip Arthroplasty, by L. Pedegana, M.D., E. M. Burgess, M.D., and M. Carpenter. Clin. Orthop. Rel. Res., 128:190-193, Oct. 1977.
2. Cutaneous Blood Flow and Its Relation to Healing of Below-Knee Amputation, by G. Allen Holloway, Jr., M.D., and E. M. Burgess, M.D., Surg. Gyn. Obstet., accepted.
3. Wound Healing after Amputation: Effect of Controlled Environment Treatment: A Preliminary Study, by E. M. Burgess,

M.D., J. Bone & Joint Surg., 60-A(2): 245-246, March 1978.

In addition to our ongoing clinical research in surgery and post-surgical amputation management conducted at the VA Hospital, Seattle, PRS is investigating, in depth, laboratory means for the determination of dynamic limb, skin and subcutaneous tissue bloodflow using Xenon 133, laser-doppler, and skin and subcutaneous pO_2 (partial pressure of oxygen) measurements. Correlation of our laboratory findings with the work of Wesley Moore, M.D., VA Hospital, Tucson, Arizona, F. William Wagner, M.D. of Rancho Los Amigos, and others, should culminate in a much more objective means of determining amputation levels preoperatively in the ischemic limb. This is a major challenge for amputation rehabilitation at this time.

The physiological suspension studies are continuing in cooperation with Dr. Fred Lippert and associates at the VA Hospital, Seattle.

The VA Hospital, Seattle, has developed a protocol for investigating muscle volume and muscle strength in the residual limb. Volumetric measurement equipment has been developed to accurately measure changes in residual limb volume. Muscle strength and electrical response of the muscles in the residual limb are also a part of this study.

A statistical review of sports and other extra-ambulatory activities of lower-limb amputees has been completed. This in-depth review of the physical activities of a sizeable number of amputees is being conducted by Jeffrey Webster of PRS, himself an athletic individual who has sustained a knee disarticulation amputation. These studies parallel the basic investigation conducted under our supervision by Professors Robert S. Hutton, Ph. D., and Doris Miller, Ph. D., at the Department of Physical Education, University of Washington, and in conjunction with the VA Hospital, Seattle.

Below-Knee Amputation with Immediate Postoperative Fitting of Prosthesis

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Wesley S. Moore, M.D.

Work on amputation level determination as a function of skin capillary bloodflow continues.

The intervening 6 months have been utilized in reestablishing the program from the San Francisco VA Hospital to the VA Hospital, Tucson: developing space, securing new equipment, and reorganiz-

ing the program in a new setting.

A full-time prosthetist is being recruited, so that the randomized study comparing immediate postoperative prosthesis with postoperative management in the controlled environment treatment (C.E.T.) unit may be reinstituted.

Hemodynamic Evaluation of Postoperative and Preoperative Amputees

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Bok Y. Lee, M.D., F.A.C.S., Frieda S. Trainor, Ph. D., David Kavner, D. Eng., John L. Madden, M.D., F.A.C.S., and Emilio Ejercito, M.D.

The Efficacy of Lumbar Sympathectomy in the Treatment of Gangrene of the Lower Limb

Work has been completed for our initial report on the efficacy of lumbar sympathectomy in the treatment of gangrene of the lower limb. A review of our records of the past 15 years (1962-1977) yielded 100 cases (111 limbs) with gangrene of the lower limb initially treated with lumbar sympathectomy. The 111 limbs were categorized into three groups: (i) toe gangrene, (ii) foot gangrene, and (iii) leg gangrene. Each limb was studied as to its outcome after sympathectomy: significantly improved without further operative treatment; required bypass surgery; required minor amputation (below the ankle); and required major amputation (above the ankle). Table 1 summarizes the pertinent data obtained.

TABLE 1.

	Area of gangrene			Totals
	Toes	Foot	Leg	
Patients	52	37	11	100
Limbs	57	40	14	111
Age (averages)	64	63	65	64
Diabetics	24	19	4	47
Limb outcome				
Significantly improved after sympathectomy	27	10	1	38
Required bypass procedure	7	3	1	11
Required minor amputation	9	2	0	11
Limb salvage	43 (75%)	15 (38%)	2 (14%)	60 (54%)
Major amputation	14 (25%)	25 (62%)	12 (86%)	51 (46%)

Patients with Toe Gangrene

Patients with toe gangrene (1 to 5 toes) showed a high percentage of limb salvage after initiated sympathectomy (75 percent) with almost half of the limbs (47 percent) being significantly improved by sympathectomy alone. Bypass procedures which were done after sympathectomy yielded significant improvement in an additional 12 percent of the limbs. Any form of amputation was thus avoided in 59 percent of the limbs with toe gangrene.

Minor amputations (7 for toe or toes, 1 foot, 1 transmetatarsal amputation) required in 16 percent of the limbs, averaging 2½ months post-sympathectomy. Thus, 75 percent of the limbs with toe gangrene were salvaged. Loss of the limb through major amputation occurred in 25 percent of the cases (9 A/K and 5 B/K) averaging almost 9 months post-sympathectomy.

Of the limbs with gangrenous toes, 24 were diabetic, 19 of whom had their limb salvaged (13 significantly improved after sympathectomy alone, 1 after bypass, and 5 after minor amputations) and 5 required a major amputation. Of the limbs salvaged, one patient shows completely healed feet almost 11 years after sympathectomy alone and one is completely healed almost 12 years after sympathectomy and bypass.

Patients with Gangrene of the Foot

In patients with gangrene of the foot, 25 percent of the limbs involved showed significant improvement after sympathectomy alone. One patient at the time of his death (myocardial infarction) almost 8½ years after sympathectomy, showed a healed foot and another patient with bilateral gangrene possessed both feet at the time of his death (M.I.) 3½ years post-sympathectomy. Two patients who underwent bypass procedures still possess their feet at 4 and 12 years post-sympathectomy. Two patients underwent minor amputation, one transmetatarsal amputation 7 years post-sympathectomy and one a toe amputation 41 days post-sympathectomy. Limb salvage occurred in 38 percent of the limbs with gangrenous feet. Limb loss through major amputation occurred in 63 percent of the cases (15 B/K and 10 A/K). In two instances, major amputation was done simultaneously with sympathectomy, and in two cases, major amputation was done simultaneously with sympathectomy, and in two cases, major amputation was done simultaneously with sympathectomy, and in two cases, major amputation was postponed for several years, one 5 years and one 6 years. Of the limbs with foot gangrene, 19 were diabetic with 6 having limb salvage (2 significantly improved by sympathectomy alone, 2 bypass, and

2 minor amputations) and 13 requiring major amputations.

Patients with Leg Gangrene

Patients with leg gangrene showed a high incidence of major amputation (86 percent) averaging about 3 months post sympathectomy. In two patients, major amputation was postponed for a considerable period of time, and 7 months and one 10 months. Only in one patient was amputation avoided by sympathectomy alone. One patient who underwent a bypass procedure died 1 day post bypass and 35 days post-sympathectomy. Of the 14 limbs with gangrene, 3 were diabetic, two of which required major amputation and one dying from pulmonary embolism after a bypass procedure.

Conclusions

The data presented in this initial report appears to support the use of lumbar sympathectomy in the treatment program of the patient with gangrene of the lower limb. These results show lumbar sympathectomy, particularly in the patient with toe gangrene, to be extremely effective in limb salvage.

In many instances, a lumbar sympathectomy alone is sufficient to initiate the healing process and avoid any amputation and when amputation is necessary, a major amputation can frequently be prevented, with a transmetatarsal or toe amputation after sympathectomy being sufficient to promote healing. Once the sympathectomy has been accomplished, evidence of the healing process can be documented by noninvasive means using photoplethysmography and skin thermistor thermometry. These noninvasive techniques, as well as noninvasive electromagnetic flowmetry, can also be used to accurately determine amputation level when required, and they therefore aid in salvaging as much of the limb as possible.

The use of lumbar sympathectomy and noninvasive quantitative measurements of blood flow in the limbs can lead to better care of the patient with peripheral vascular disease, with consequent salvage of many limbs.

Engineering Applications in Orthotic and Prosthetic Treatment of Musculoskeletal Defects
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Rehabilitation Medicine Service
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E. Byron Marsolais, M.D., Ph. D., and Eduard Schulz, E.E.

Applications of Motion Analysis in Orthotics and Prosthetics

1. *Comparison of Implanted Electrical Stimulation (Neuromuscular Assist) to Other Methods of Treating the Equinovarus Foot*

This study, which began in 1971, compared the Neuromuscular Assist (implanted) Electronic Brace with four other ankle-foot orthoses. It has now been completed. Orthoses compared were: (i) the Texas Institute of Rehabilitation and Research (TIRR) polypropylene device which has also been referred to as the "Engen brace" in these reports; (ii) the external FEPB (Functional Electronic Peroneal Brace); (iii) the conventional metal double-upright orthosis; (iv) the VAPC Shoe Clip; and (v) no device at all. The orthoses were compared on a pre-selected and screened group of hemiplegics rather than at random.

A total of 7 patients were implanted with electrodes. The results showed the NMA gave the greatest velocity, stride length and cadence, with a more normal heel and toe contact time. There tended to be some overcorrection of the varus deformity. All orthoses had acceptable correction of the hemiplegic varus deformity.

It was concluded that the NMA represents a clinically usable method for dropfoot correction. Further use must be by the preference of the individual patient and surgeon. The FEPB proved too complicated for our patients to use outside the hospital (see BPR 10-27, Spring 1977, p. 173).

2. *Foot Contact System*

Our foot contact system for gait analysis is providing information to physicians on a limited clinical basis. About 70 patients have been analyzed.

In reference to a reader's question regarding double support (BPR 10-28, Fall 1977, page 212): *Two* periods of double support occur within a gait cycle. This Laboratory defines Left Double Support as that period beginning with left heel strike and ending with right toe-off, leading to single support on the left leg during swing phase of the right. The second or Right Double Support period is initiated by right heel strike and terminated by left toe-off. In normal gait, these periods are equal, so *total* double support time during a cycle is *double* the value given for *one* leg by Equation [3]. In pathological gaits, these periods often differ markedly. Monitoring of changes is important in assessing progress of a patient.

3. *Stimulation of the Paralyzed Hip to Return Functional Use*

Functional electrical stimulation of the paralyzed hip has to date involved two patients. One below-knee amputee has a fixed knee contracture and was unable to walk with an artificial limb. After

stimulation of the rectus femoris muscle on a chronic basis, the patient was able to walk without support.

Another patient lacked hip flexion and the iliopsoas was stimulated. Good hip flexion was obtained; however, the patient did not wish to leave the electrodes in on a prolonged basis. The electrode breakage problem we had previously been experiencing has been much improved. A microprocessor-based stimulation system is nearing final stages of construction, and will be used in the study for programed hip and knee control in the hemiplegic patient.

Three-Dimensional Automated Motion and Joint Force Analysis

Using a three-dimensional computer based technique for automated motion/force analysis of human walking, surface electromyographic electrode placement has been studied and optimal spacing and positioning of these electrodes determined. Intramuscular electrodes, however, appear to be superior.

Further testing of the Selspot system for determining the position of the body in 3-dimensional space has indicated that the system is not usable in its present state for gait analysis. It is our opinion that modifying the present electronics can convert it into a valuable tool for gait analysis.

Other Activities

The Cleveland Veterans Administration Hospital Motion Study Laboratory is one of six facilities involved in the clinical evaluation of the VA/Rancho Los Amigos Gait Analyzer. The unit calculates the parameters of velocity and right and left single-stance duration. Normal subjects and patients with a variety of gait problems were evaluated with the analyzer while they walked over our 6-m walkway. Concomitant data were gathered using the Cleveland Foot Contact System. It is our opinion that the analyzer is an excellent initial effort to meet a serious need. We feel that, with some modification, the system will become a very important adjunct to patient evaluation.

A program has been established for the rotation of medical students from Case Western Reserve University to the Motion Study Laboratory. Students are exposed to the mechanics of normal and pathological gait, as well as to the various systems available for gait analysis. The rotation is 6 weeks in length.

Patient Evaluation of a Functional Electrical Stimulation Hand Orthosis

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Introduction

The purpose of this project is to develop and evaluate a system employing electrical stimulation to provide controlled prehension and release in the high level spinal cord injury patient. The function and operation of the unit was described in detail in the previous progress report. In this period, development of the miniature stimulator and work with patients using prototype systems has continued.

Stimulator Development

The stimulator is being constructed in two versions; as a laboratory-based instrument and as a device for use by patients. The philosophy for constructing these two versions was discussed in the previous report. Briefly: the laboratory based unit is used initially to evaluate the patient's performance and determine proper stimulation parameters; these parameters are then set into the miniature unit. The patient units are designed to operate in the same manner as the laboratory-based unit, but are small and portable.

The laboratory unit has been completed and is in use for patient studies.

The miniature units have been completely designed and the first unit is nearing completion. The miniature stimulator's electronic circuits are implemented on three printed circuit boards. These boards are approximately 3 × 4½ inches and are stacked vertically over each other. One of these three boards has been assembled and completely tested while the other two are currently being etched commercially.

The initial patient device will be packaged in an off-the-shelf plastic enclosure 6 in long, 3 in wide, and 2 in high. This unit will be used to obtain preliminary patient feedback on possible improvements in system packaging, cabling, attachment, etc. Later a custom enclosure will be made which will be smaller and will make patient attachment easier; e.g., holster or belt attachment.

Operation of the System

The operation of the system was described in detail in the previous report. Emphasis in this period has been placed on two spe-

cific aspects of the control logic; that associated with the patient's input to the system, and that associated with feedback of the control state to the patient. Control logic enables the patient to transform movement of either his head or shoulder into the proper stimulus for activation of the muscle, and also to activate functions which simplify the patient's control task. These functions enable the subject to turn the system on and off, to specify his zero reference position, and to hold a desired control output independent of his shoulder position.

The circuitry has been generated to provide two alternative control schemes. The difference in these schemes relates to the means by which the patient regains volitional control over the stimulator from the HOLD mode, and the audio feedback cues used to signal the state of the control logic. In both control modes, a low-level myoelectric signal (MES) triggers activation of the HOLD function and movement of the proportional control is ineffectual.

Two alternative control schemes are provided for regaining control. In the first scheme, the patient signals the desire to regain control with a low-level MES, but must "search" with the proportional controller to "find" the position at which he originally "held". The second control scheme enables the patient to regain control at any position of his shoulder (or head) by producing a low-level MES, which in effect provides a floating reference position. In either case, the subject can choose to rereference the zero position by producing a high-level MES twice in succession. The first signal turns the system off; the second turns the system back on, resetting the reference position of the proportional controller to the position which was sensed when the second high-level MES was generated.

Experience with the present system has demonstrated the need to provide the subject with information regarding the state of the control logic. Audio tones have been chosen to signal changes in the operating mode; e.g., rezero, enter hold, regain control. Control logic to perform these control and audio feedback functions has been completed in this period.

In the next period, we will begin to establish the advantages and limitations of each control scheme. The present intention is to investigate both schemes in every patient, since both alternatives are available by a simple programing change in both the laboratory and patient stimulators.

Laboratory Development

Initial work has begun in the process of linking the instruments in the ward laboratory with the hospital's central research com-

puter. The computer, a PDP-11/45 with 15 Mbytes of disk storage, is a multi-user system and simultaneously performs tasks for several investigators. The primary objectives for connecting to the computer are to assist in: (i) organizing and performing routine patient tests (e.g., evaluation of a subject's muscle/electrode characteristics), (ii) organization and storage of test results, (iii) implementing new stimulation and/or control schemes with a minimum of additional hardware, and (iv) display and analysis of stored data.

Patient Evaluation

Two C-5 quadriplegic patients continue to be involved in these studies, using the prototype system described in the previous report. These patients have been active participants in the design of the new stimulator systems, both as users expressing the features of construction and operation that they feel are important, and as subjects for experimental verification of proper operation of the device. These patients will be the first recipients of the new systems which will be completed in the next period.

Research and Development Project on Advanced Orthotic Devices for Adult Paraplegics

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Martin T. Prast

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No progress report was submitted by this contractor for this report period.

Evaluation of Electrical Techniques for Stimulation of Hard Tissue Growth
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Over the past 12 months work has continued on the following projects:

Electrically Injected Silver Ions as a Local Bactericidal Agent

1. The use of electrically injected silver ions as a local bactericidal agent has been under continuing investigation, both at the basic and the clinical level. At the basic level, we have re-evaluated the electrical parameters necessary for the bactericidal effect, using a more sophisticated electrode measuring system. We have found that the voltage on the silver electrode must be a minimum of 250 mV positive for the effect to occur. We have also found that the effect, in vitro, can be produced with the application of as short a time as 2 minutes. Presumably, the amount of silver ions ejected in this time is sufficient to inhibit compfetefy the bacteria in the target zone. While this may not be possible in vivo, the information may prove useful in our future studies on the mechanisms of the silver bactericidal effect.

We continue to attempt to develop techniques enabling us to expand the diameter of the zone of inhibition, but have not been successful thus far.

The clinical evaluation of the electrically injected silver ion as a bactericidal agent has passed from the experimental to the application phase. We are now using this treatment against all of our osteomyelitis cases that require treatment. In the past 6 months, we have treated four additional patients (two with co-existing non-unions) and all have been successful. Two more patients are presently under study, and we are receiving referrals from other VA Hospitals specifically for the infected non-unions of long bones.

A complete report on our clinical usage of this technique has been accepted for publication in the Journal of Bone and Joint Surgery.

We are attempting to expand the clinical situations in which the technique is used, to include such cases as bladder infection in paraplegics, burns, and the recalcitrant skin ulcerations such as severe decubiti, etc.

2. In a related study, we are determining the local bactericidal efficiency of various silver compounds as additives to methylmethacrylate bone cement. Total joint replacement necessitates the use of such a cementing agent which, in its setting phase, is exothermic to the extent of producing a narrow zone of bone necrosis surrounding the cement. This, coupled with the large mass of foreign material (cement plus prosthetic device), makes any local post-operative infection a clinical disaster. Various techniques have been employed to reduce the incidence of such infections ("clean room" operating techniques, intravenous antibiotics, addition of antibiotics to the cement, etc.). All have been less than totally effective since various studies list the present incidence of post-operative infections in total joint replacement to between 1 and 5 percent.

We theorized that the addition of silver compounds to the cement may be locally bactericidal by a diffusion process alone. Such a technique would be superior to the addition of antibiotics to the cement, since the exothermic reaction temperature that occurs with setting inactivates these complex organic molecules, but would have no effect upon inorganic silver salts. We have evaluated both the ability of silver ions to diffuse out of the cement (in sufficient numbers to be locally bactericidal) and the mechanical properties of the silver compound and methylmethacrylate mix. Silver salts that have been evaluated (in concentrations ranging from 0.05 to 1 percent) are: chloride, oxide, sulfate, and phosphate. We found that silver sulfate exhibited the maximum bactericidal effect for the longest period of time following implantation, and that this compound had no effect upon the mechanical properties of the methylmethacrylate. Antibacterial effects of Ag_2SO_4 methacrylate produced a visible, measurable, zone of inhibition in culture plates against both gram positive and gram negative organisms (Fig. 10). Some antibacterial activity was still obtainable after 49 days of soaking the silver methacrylate in warm normal saline, indicating a prolonged activity period.

At this point the concept of adding silver salts to methylmethacrylate bone cement as a local antibacterial agent appears to be both effective and without effect upon the mechanical properties of the cement. Biocompatibility studies will be started in the near future: should these indicate that there are no severe local toxic effects resulting from the added silver (as compared to the methylmethacrylate alone) we hope to arrange actual testing using total joint replacements in dogs (in cooperation with Cornell Veterinary College).

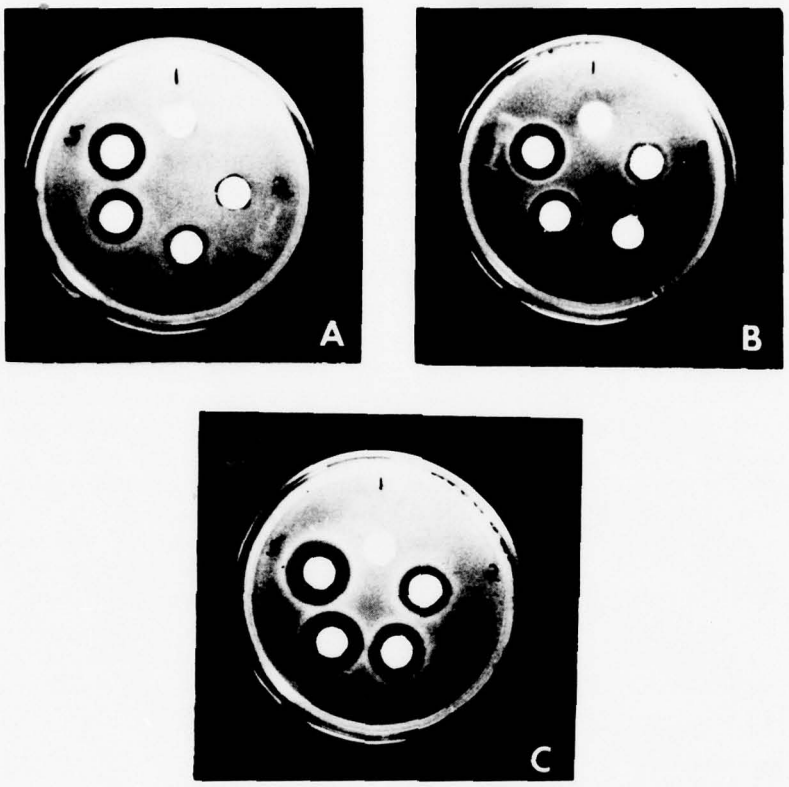

FIGURE 10.—Bacterial culture plates showing inhibition of: (A) *Staphylococcus aureus*; (B) E. Coli, and (C) Pseudomonas aeruginosa, by silver antibacterial bone cement (SABC). In these tablets, Ag_2SO_4 was added to Simplex-P Radiopaque Bone Cement in concentrations of 0, 0.05, 0.1, 0.5, and 1 percent, reading clockwise from the top tablet in each dish.

The entire concept of silver ions as effective broad-spectrum local antibacterial agents leads to a number of possible clinical applications of interest beyond those presently under study. These would include the use of silver coatings on prosthetic attachment devices designed to provide bony anchors for attachment by penetrating the skin barrier. The silver would appear to obviate the problem of local bacterial infections at this site, and its ability to be attached to a variety of fabric materials may provide for dermal ingrowth directly into the attachment.

Electrical Stimulation of Bone Growth

3. The electrical stimulation of bone growth in the human by low-intensity direct current continues to be evaluated. A full report was published (Clinical Experience with Low Intensity Direct Current Stimulation of Bone Growth. Clin. Orthop. & Rel. Res. 124: 75-83, 1977. Becker, R. O., J. A. Spadaro, and A. A. Marino) last year and a number of additional cases have been carried to completion since then.

An international meeting with the theme of "The Mechanisms Involved in the Stimulation and Control of Regenerative Growth and Their Clinical Application" is being planned for the Fall of 1979. This will bring together a number of lines of inquiry in basic research, such as stimulation by electrical factors, chemical growth stimulation, and inductive substrate stimulation, and will relate them to ongoing clinical research such as the electrical stimulation of bone growth. It is expected that such a meeting will hasten the clinical application of additional techniques and increase the scope of such applications to include tissues other than bone.

Acceleration of Bone and Soft Tissue Healing by Electrical Stimulation

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Helen Hayes Hospital
Biomechanics Research Unit
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George Van B. Cochran, M. D.

This project is designed to study the effects of electrical stimulation on the healing of experimental non-union in canine bone. The object is to increase understanding of clinical applications of this new technique in treatment of non-union, especially in those major injuries involving large defects in bone.

During the report period, work on further adaptation of the investigator's model has continued. The prior technique, originated for large mongrel dogs, now has been modified and tested successfully for use in laboratory bred beagles. This advance will improve reproducibility and uniformity of the model so that various effects of stimulation parameters, including electrode design and placement, can be compared more effectively.

In Vivo Loading of Knee Joint Replacement

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Victor M. Goldberg, M.D.

Since our last report there has been a change in the methods of procedure. Formerly, we stated specifically that we would determine the loads borne by a total knee joint replacement in the human knee by instrumenting a dual condylar prosthesis system of our own design. However, the prostheses already designed and fabricated were destroyed in the process of micropolishing by an outside concern. Because of this unfortunate incident, we were faced with the necessity of remanufacturing our total prosthetic supply.

Instead of simply remanufacturing what was becoming a somewhat obsolete design in the light of recent prosthetic advances, we utilized this period to totally re-evaluate the project. The results of this re-evaluation indicated that the most common and useful prosthetic device currently being utilized was that of the total condylar femoral design. Because of this, it was decided that the investigation should proceed along the lines of determining the load data from the most currently utilized implant devices. Based on this decision, it was further decided that the study could best be fulfilled by utilizing a standard femoral prosthetic device of commercial manufacture, and shifting the design effort to the construction of a tibial component that would incorporate a normal tibial plateau normally associated with the given prosthetic femoral component, yet be capable of containing all the necessary telemetry electronics to telemeter out the desired in vivo load data. Our current efforts are now directed towards this approach.

Although this represents a significant engineering change in the project, we feel it also represents a significant improvement in the ultimate ability of the project to give current meaningful clinical data, which is the stated purpose of the study.

Orthopedic Implant Device Retrieval and Analysis

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We are continuing to retrieve and analyze orthopedic implants removed from patients at the Veterans Administration Hospital, New Orleans, La., and the Veterans Administration Hospital, Columbia, South Carolina. Parts of the implants retrieved from this program, the screw plate type devices, were incorporated into a study to determine the clinical significance, if any, of crevice and/or fretting corrosion. All devices were either routinely removed or considered "clinical failures." No mechanical failures of any of the devices were observed. Correlations of the time in situ, reason for removal, and degree of corrosion was performed. Correlations of chemistry microstructure, micro- and Rockwell hardness, and tensile properties, were also performed.

Screws and their respective holes were graded for severity of corrosion, from none to very severe, using a numbering system. The devices were next subjected to basic metallographic examination in which inclusion content and grain size were determined. Chemical compositions were also determined on some of the devices. Macro- and microhardness measurements were made on all components. Tensile properties were determined on some of the Jewett-type nails, using a microtensile bar sample machined from the proximal plate area. Scanning electron microscopy was performed on several areas of corrosion to distinguish the differences between crevice and fretting corrosion.

The following conclusions were drawn from this study:

1. Crevice corrosion was observed in all of the 316L stainless steel devices studied. It was apparently not clinically significant for those in situ up to 16-18 months; that is, it did not contribute to the clinical failure. However, it may be a contributing factor to failure of devices left in situ for longer periods of time;
2. No correlation between degree of corrosion, time in situ and reason for removal was observed in these cases;
3. The potential effect of copper on the mechanical properties of 316L stainless steel is such that it should be brought under ASTM specifications for chemical composition for special quality material;
4. A good correlation, in general, was shown between tensile properties, microstructure, and both Rockwell and microhardness;
5. Crevice and fretting corrosion are two separate and distin-

guishable mechanisms, but may act simultaneously and may become indistinguishable from each other at low magnifications (<50X).

Intramedullary rods—In addition to the screw-plate type devices, a study was made of 25 cases of open reduction and internal fixation of several fractures using the AO intramedullary rod. Seven rods have been retrieved during the normal clinical care of patients. Five of these rods have exhibited cracks emanating from the proximal end of the longitudinal slot. It was noted that the crack had progressed a varying amount circumferentially for each case, and that one case had resulted in the proximal portion becoming detached from the remainder of the rod during removal. This necessitated leaving the remaining distal portion implanted in the patient. A complete failure analysis including detailed review of all radiographs, medical records, surgical procedures, and metallurgical analyses of the implants was performed on each case. All implants were fabricated from stainless steel and no gross chemical or microstructural deviations from accepted standards were identified. It was interesting to note that the rods were fabricated from welded tubing. Non-destructive dye penetrant inspection revealed no secondary surface cracking. At the present time the results of this investigation are still under analysis, and no definitive conclusions have been reached.

Studies of Normal and Abnormal Motion

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Mary Patricia Murray, Ph. D.

This research began July 1, 1964, under the sponsorship of Veterans Administration Medical Research and Development. In FY 1978 the program's funding was transferred to the newly established VA Rehabilitative Engineering Research and Development Service, Washington, D.C.

The major emphasis this past year has been in the area of quantitatively evaluating multiple components of functional performance of patients with severely disabling arthritis, before and after various types of total joint replacements. The multifaceted tests of functional performance are done preoperatively and at specified periods up to 4 years postoperatively whenever possible. The multifaceted patient testing includes measurements of: the strength of the

muscles spanning the operative joint; joint mobility; weight-supporting activity during upright posture; the amount of force applied to canes or crutches; and multiple simultaneous displacement patterns and temporal components of gait. All of these measurements are compared with standards of normal variability which we have previously established.

We believe the tests which we have devised provide extremely sensitive indicators of the level of improvement or decline in overall function, and such quantitative information is essential for a critical analysis of a given procedure or in comparisons of the results obtained with different procedures.

Total Hip Joint Replacement Study

This year, we published a study comparing multiple aspects of functional performance of 143 patients with McKee-Farrar, Charnley, and Müller total hip replacement, before and 6 months after surgery (*1*). A comparison of the three groups revealed some early postoperative differences.

The patients with Charnley implants had the smallest average total postoperative ranges of hip motion in all three planes, while the patients with McKee-Farrar had the largest average excursions in the sagittal and transverse planes, and those with Müller had the largest excursions in the frontal plane.

The group with McKee-Farrar replacement had the most, and the group with Charnley the least, improvement in hip adductor muscle torque, but the three groups were similar in their improvement in hip abductor muscle torque.

The group with Charnley replacement had the most patients who improved in weight-supporting ability on their operated limbs, but the average amount of improvement in weight-bearing ability was similar for the three groups.

There were no consistent differences among the various components of walking, or in the amount of force applied to canes or crutches, to indicate that one group's overall walking performance was better than the others. On the basis of average values, each group improved in every component of function, and it is gratifying that, except for a few patients who developed postoperative infection, each patient could be considered to have had successful reconstruction 6 months after surgery.

While the functional performance during the early postoperative period after total hip replacement is important, particularly for the elderly and those with limited life expectancy, evaluations of the long-term effects are of equal importance. Accordingly, we have made substantial progress in a study of functional performance

of 104 patients with Charnley and Müller total hip replacement, before and 6 and 24 months after surgery. We have collected all of the records and are in the process of analyzing the data. Preliminary results indicate a significant amount of improvement in all aspects of functional performance 6 months after surgery and also further improvement between the 6th and 24th postoperative months.

Roentgenographic Measurements after Müller Total Hip Replacements

A study correlating roentgenographic measurements of prosthetic component positioning with hip muscle torque and mobility, in 52 patients with Müller total hip replacement, was completed and published in March 1977 (2). Compared with the normal side, the average position of the center of the prosthetic head was more medial and superior in the pelvis, and the greater trochanter was more distal and lateral. Increasing the neck length (distance from the prosthetic head center to the lesser trochanter) and a more distal position of the greater trochanter, were among the measurements which related favorably to patient function. More superior placement of the center of the prosthetic head in the pelvis was associated with a more superior position of the lesser trochanter, which related adversely to function. Although the final position of the prosthetic components depends partly on the anatomy of each patient, it also depends on the prosthetic components used and the manner in which the procedure is performed, both of which are dependent on the judgment, skill, and philosophy of the surgeon. The results presented in this paper should provide useful guidelines to orthopedic surgeons.

During fiscal year 1977, we will have completed more than 215 extensive multifaceted tests of functional performance of patients before and during the early and late postoperative periods following various kinds of total hip and total knee replacements.

Kinesiological Measurements of Functional Performance Before and After Geometric Total Knee Replacement (3)

In this followup of 20 cases, tests of functional performance were conducted before surgery and 3, 6, and 12 months afterwards. Measurements included joint motion, extensor lag, isometric strength of the knee flexor and extensor muscles, cane or crutch force during walking, selected measurements of free-speed and fast walking, and weight distribution between the feet during 1 min of comfortable standing. These measurements, except for range of motion, were compared with standards of variability for normal men in appropriate age groups.

The group of patients with rheumatoid arthritis improved more than those with osteoarthritis, but they did not generally reach the functional level of the group with osteoarthritis, and neither group reached the lower limits of normal variability 1 yr postoperatively.

The findings also suggest the importance of emphasizing maintenance of full knee extension in the postoperative regimen as well as continuing knee muscle strengthening exercises for a prolonged postoperative period.

On the average, both groups gained knee extension, lost knee flexion, and gained isometric knee flexor muscle strength postoperatively. Every patient with osteoarthritis lost extensor muscle strength one year after surgery, while most with rheumatoid arthritis gained. During quiet standing, most patients had straighter knees postoperatively and bore a greater percentage of body weight on the operated limb. Patients with rheumatoid arthritis improved more than patients with osteoarthritis in the type and amount of force applied to canes and crutches. Most patients walked faster postoperatively, took longer and more rapid steps, improved the pattern of knee motion used, and had smoother forward, lateral, and vertical head motion.

Maximum Isometric Knee Flexor and Extensor Muscle Contractions

We have completed a study documenting the ranges of normal variability in isometric torque of the knee flexor and extensor muscles during maximum isometric contraction. This study was published in June 1977 (4).

While many studies concerning the strength of the knee flexor and extensor muscles have been previously reported, most of those have dealt with the strength of young adults. The 48 subjects in our study were healthy men in age groups from 20–35 and 45–65 yr of age.

Isometric torque of the knee flexor and extensor muscles was recorded for 5 sec at knee joint positioning of 30, 45 and 60 deg. For each contraction, we measured the amplitude and duration of peak torque, and the time from the onset of the contraction to the time of peak torque. The paper describes the differences in individual patterns of torque output with respect to time, since little information has been reported quantifying the nature of the dynamics of the forces generated during isometric contraction of individual subjects. Careful scrutiny of all of the patterns of torque output over time indicated that no single pattern could be considered representative, and this was usually true even within all of the tests of a given subject. Peak torque was usually maintained for less than 0.1 sec and never longer than 0.9 sec. At each knee

joint position, the mean extensor muscle torque was higher than the mean flexor muscle torque for both age groups. And, at each knee joint position, the strength of the men in the older age group averaged 75–80 percent of that of the men in the younger age group.

This information will contribute to an increased understanding of the dynamics of the motor response *during attempted maximum* isometric contraction. In addition, this study provides standards of normal variability to serve as baselines for assessing the strength of patients with knee joint disabilities.

Gait Patterns of the Parkinsonian Patient

We have finished collecting data for a study characterizing the gait of patients with parkinsonism during free-speed and fast walking, *and are* in the final stages of data analysis.

In order to identify the specific gait components which relate systematically to the severity of the disability, the 44 patients were categorized into groups with mild, moderate, and severe disability on the basis of their independence in self-care activities.

The measurements of walking performance of the groups will be compared to those of an appropriate *control group of normal* men.

This study will provide guidelines for critical evaluation of the efficacy of various treatment procedures directed at improving functional performance of patients with parkinsonism.

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Electrophysiological Techniques in Evaluation and Correction of Neuromuscular Defects

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Within this project there are several investigations in various stages of progress. These are devoted to investigating gait patterns during ascending and descending stairs, gait patterns during level walking at various walking speeds, biomechanics of normal human locomotion, and the function of the patello-femoral mechanism after arthroplasty.

Ascending and Descending Stairs: A Pilot Study

A pilot study concerning the ascending and descending of stairs has just been completed. Electromyographic patterns of selected lower-limb muscles were investigated in male athletes and non-athletes during ascending and descending of stairs and level walking. Significant variability is found between the individual patterns for ascending and descending, although primary patterns can be identified. Some of the primary patterns found are different from those previously reported in the literature. The atypicalities did not appear related to athletic training nor to the incidence of knee injury/surgery among the athletes. All gaits appeared kinematically similar.

Biomechanics of Normal Human Locomotion

Twenty normal subjects have been studied while they were walking on a level surface at fast, normal, slow, and very slow speeds. Preliminary results indicate that a small percentage of the population has muscle synergy patterns appreciably different from the accepted "norm." Changes in speed of progression from slow to fast do not in general cause a major alternation in muscle synergies. However, gait patterns at slow speeds mimic some pathologic gaits.

A detailed method for assessing the actual muscle forces and joint torques during ambulation is now being developed. It will estimate these quantities from measured kinematic and electromyographic data.

Patello-Femoral Mechanism

The investigation of the patello-femoral mechanism after arthroplasty has just been initiated. Its main goals are:

1. To determine the most effective surgical approach to the

patello-femoral compartment with total knee replacement arthroplasty. Effectiveness is defined as the degree of pain relief during transfer and stair climbing activities.

2. To define clinical, radiographic, dynamic resistance, and quantitative EMG criteria for determining pre-operatively the preferred surgical approach to the patello-femoral compartment in individual patients.

Maxillofacial Restorative Materials and Techniques
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During the period of this report (June 30, 1977, to Dec. 31, 1977) research has been pursued on a broad front. It has included fundamental molecular polymerization mechanisms for optimum biomechanical replication of living tissue, controlled fabrication technology, and toxic and carcinogenic assessment of the materials. The former are indispensable to providing sound scientific data that will assure the reproduceability of high quality prostheses compatible with anatomical tissues. The latter is a high priority effort in response to the more stringent statutory requirements for medical devices imposed by the recently enacted Medical Devices Act (1976).

Within this broad front, the project has been developing and defining the technical/spectral aspects of intrinsic pigmentation for cosmetic matching that would suit the prosthetist specialist, and ascertaining the merits and shortcomings of the prostheses when they are worn for reasonable lengths of time. For the latter effort, the project has also served as a production facility capable of producing orofacial prostheses for 10 new patients per week (500 yearly). With modest expansion, the present fabricating equipment could accommodate all of the requirements for the entire Veterans Administration, with quality control and performance standards and records that are believed to be acceptable to the Food and Drug Administration, with the data now being accumulated.

Safety and Performance of Maxillofacial Prostheses—Conformity with Medical Devices Act (1976)

Polydimethylsiloxane prosthetic materials developed in this project have been shown to be non-toxic to excised human orofacial tissues taken from patients (ages 21 to 59) using a novel test

system involving direct-patient assessment by tissue culture technique. The test system, aimed at accumulating data for conformity with the regulatory requirements of the Toxic Substances Act of 1976 (1) for medical devices and cosmetic applications, discriminates between non-toxic polydimethylsiloxane elastomers and incidental sampling of highly toxic polyvinyl chloride formulation (2) and polyurethane composition used for maxillofacial prosthetics. In particular, the new test system, devised in this project, circumvents the use of, and dependence upon, conventional animal testing. Conventional animal testing involves various animal species of controversal acceptance as being correlatable and valid to human physiology and toxicology; such animal tests take up to several years to attain biometric validity, and involve costs prohibitive for use in marketing medical devices and especially those for maxillofacial reconstructions.

Before the new law was enacted, the Food and Drug Administration initiated anticipated standards development activities for 15 groups of medical devices, including orthopedic and surgical implants, dental materials and devices, and others (1). This portion of the project has been designed (3) to provide proof and data for

TABLE 1.—*Accumulation of Selected Human Excised Tissue for On-going Toxicity Testing in Progress*[a] *with PDMS (Polydimethylsiloxane Elastomer) Prostheses*

Patient Code	Age	Sex	Race	Tissue	Comment
A. Control Group (no carcinoma)					
DG	46	M	W	Gingiva	Routine dental
CN	62	M	W	Gingiva	Routine dental
HJ	62	M	W	Gingiva	Routine dental
RX[b]	21	M	W	Gingiva	Routine dental
PX	19	F	W	Gingiva	Routine dental
BJ	48	M	W	Gingiva	Routine dental
OE	20	F	W	Gingiva	Routine dental
HD	51	M	W	Gingiva	Routine dental
TJ	20	M	W	Rhino-mucosa	Surgery
B. Carcinoma cases (or surgery)					
JC[c]	54	M	W	Rhino-mucosa	Surgery
FW	–	M	W	Rhino-mucosa	Surgery

Goal: Biometric Data Base shown in Figure 12, with at least 32 patients in each matrix block.

[a]The table shown here is only a select listing to illustrate the accumulating cohort.

[b]Used as reference standard because of youth and no adverse physiological profile.

[c]First case of direct patient testing: see Figure 13.

safety, involving toxicity and carcinogenicity testing on the excised orofacial tissues, and for performance, in conformance with the regulations. This entails well-defined materials and product specifications, and controlled fabrication processes with detailed record keeping. The statutory requirement also applies to proof of safety and performance even after repeated hygienic maintenance which can result (for certain materials) in chemical attack to the prosthesis with attendant toxicogenic reactivity to human tissues. Illustrative of the unique chemical resistance of the dimethylsilicone configuration (4) used exclusively in this project, limited comparisons have been made with the competitive maxillofacial materials, namely, polyvinyl chloride plasticized with low molecular weight additives (5) and polyurethane polymerized to low modulus products (6).

Testing Details and Results

Table 1 summarizes the accumulation of selected human excised tissue from over 40 candidate samplings to develop the pool (or cohort[a] as this is currently termed in studies on human exposure to toxic chemicals or environments) from which a biometric data base can be periodically evaluated for risk/benefit estimates, for tracing special susceptibility such as allergenicity, and for tracing any harmful effects that may have been due to sub-standard materials or improper fabrication.

The accumulating data base in depicted in Figure 11 (which lists three principal groups of human tissues that are relevant to use of biomaterials including skeletal extensions) and in Figure 12. Group I concerns safety and performance to mucosal tissues, which may not themselves reveal toxic or growth inhibitive effects, but through which migratable toxicants could reach target tissues in Group II, giving rise not only to organ toxicity but also chemical oncogenicity. Considering that a significant segment of the patients contributing to the accumulating pool or cohort have on-going carcinoma that could metastasize, it becomes important to include the Group II target cells. This becomes especially true for the bladder organ which has come into much prominence from industrial and environ-

[a]The term cohort, according to current usage by the National Institute of Occupational Health, relates to a methodology of assembling biometric information on a target group of individuals from which causative factors leading to pathological conditions are extracted for establishing risk/benefit value judgment. This same methodology is used in this project to obtain the analogous risk/benefit, using actual excised human tissues. Thus, if it can be shown that 32 patient tissues times 32 prostheses showed negative toxicity (using, of course, positive controls) then such data could constitute a basis for FDA approval of the specified PDMS formulation and the certified polymerization conditions.

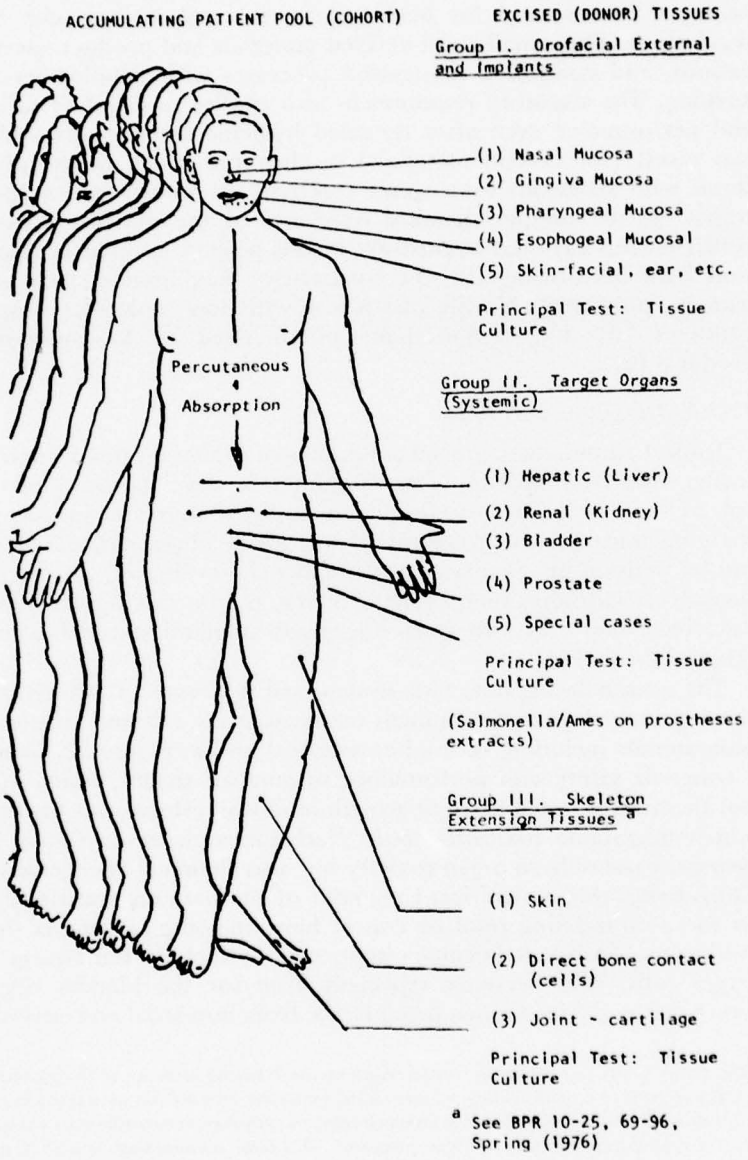

FIGURE 11.—Human excised (donor) tissue from orofacial patients subjected to related tissue culture toxicity test, involving mucosal and target organs for the biometric data base shown schematically in Figure 12. The method is applicable to skeletal extension prostheses.

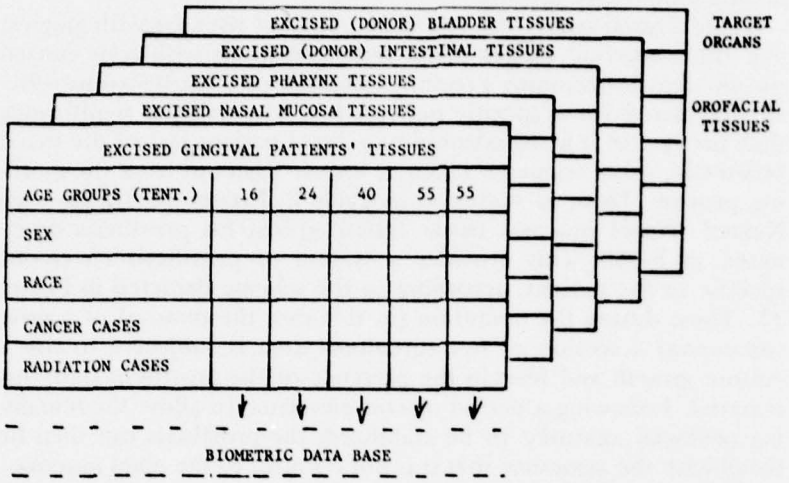

FIGURE 12.—Biometric Data Base: direct patient-donor tissue and target organ cell toxicity-testing for developing an accumulated cohort of non-toxicity for FDA review and approval (11).

TABLE 2.—*Summary of Selected Tissue Culture Tests on PDMS Fabricated Prostheses*

Composition	No.	Prostheses for patient	Form	Patient (donor)	(age)	Tissue	Result (toxicity)
L-124-21-S-3	P-621	S.N.	Nose	R.L.	(59)	Gingiva	Neg.
L-124-21-S-1	P-624	M.A.	Orbit	R.L.	(59)	Gingiva	Neg.
L-124-21-S-4	P-640	R.E.	Orbit	R.L.	(59)	Gingiva	Neg.
L-124-21-S-4	P-641	K.R.	Ear	R.L.	(59)	Gingiva	Neg.
L-124-21-S-4	P-643	B.N.	Ear	R.L.	(59)	Gingiva	Neg.
L-124-21-S-3	P-621	S.N.	Nose	H.E.	(51)	Gingiva	Neg.
L-124-21-S-4	P-640	R.E.	Orbit	J.C.	(54)	N-Mucosa	Neg.
L-124-21-S-4	P-641	R.E.	Orbit	J.C.	(54)	N-Mucosa	Neg.
L-124-21-S-4	P-653	B.N.	Ear	J.C.	(54)	N-Mucosa	Neg.
Direct Prosthesis-to-Patient[a] (Figure 13)							
L-124-21-S-1	P-689	J.C.	Nose	J.C.	(54)	N-Mucosa	

[a]A first in this project, i.e., testing the formed prostheses on the patient's excised, in this case orofacial tissue, cultured and stored for testing.

mental long term exposure.

Table 2 summarizes the test data obtained thus far with gingival and rhino-mucosal tissues taken from the pool, with tests carried out in what is becoming a routine clearance of a fabricated prosthesis designated for a specific patient. It is of particular significance that the system is being adapted to a direct-patient test of the fitted prosthesis, using segments taken as excess flash-out from the molding process. Thus, as indicated in Table 2, Patient JC has his own N-nasal (Nose) mucosal tissue tested against his prosthesis designated as P-689. This provides a system of prosthesis check-out specific to the patient, according to the scheme depicted in Figure 13. Thus, during the operation (in this case the removal of a nose carcinoma) a section of non-carcinoma area is subjected to tissue culture growth and tests in the presence of the prosthesis flash-out material. Following a period of convalescence to allow the remaining orofacial anatomy to be stabilized, the prosthesis can then be fitted with the assurance that it is not harmful to the nasal mucosa.

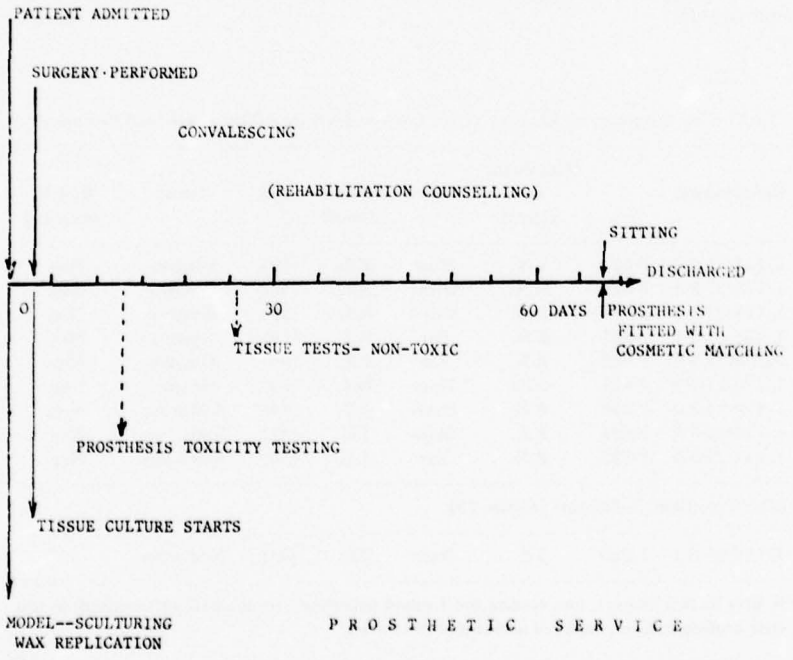

FIGURE 13.—Direct patient tissue-prosthesis testing, using excised orofacial tissue (gingiva, rhino-mucosa, etc.) taken during surgery. Protocol formally initiated with Patient JC (10/13/77) (Table 1).

TABLE 3.—*Summary of Tissue Culture Tests on Competitive Polymers for Orofacial Prostheses.*

Chemical Designation	Code	Source	Form	Patient source	(Age)	Tissue form	
Polyvinyl chloride (PVC) plasticized	PVC-121	Esschem Co.[a]	Molded Sheet	R.L.	(59)	Gingiva	Highly Toxic
	PVC-121	Esschem Co.[a]	Molded Sheet	J.C.	(54)	N-Mucosa	Highly Toxic
Polyurethane (Dermathane)	L-124-91-A (untreated)	Gonzalez[b]	Nose	S.T.	(60)	Gingiva	Highly Toxic
				S.T.	(60)	Gingiva	Highly Toxic
	L-124-91-B	Gonzalez[b]	Nose	J.C.	(54)	N-Mucosa	Highly Toxic
	(NaOCl)[c]			J.C.	(54)	N-Mucosa	Highly Toxic

[a]Prototype III made according to Sweeney, A.B., et al. (Reference 2) Evaluation of Improved Maxillofacial Prosthetic Material. J. Prosthetic Dentistry, 27, 297-305, March, 1972.

[b]Obtained from Dr. Juan B. Gonzalez (Letter, Lontz, John F., April 10, 1977).

[c]Hygienic maintenance in sodium hypochlorite (USP).

Table 3 summarizes an on-going surveillance of competitive maxillofacial materials, namely polyvinyl chloride with plasticizer (5, 7) and polyurethane which depends upon dibutyl tin dilaurate, a toxic substance (8), to effect the polymerization (6). This surveillance is deemed appropriate for providing technical guidance in adjusting these materials with their catalysts and other components that would eliminate the contributing toxic factor or factors.

Clinical Rehabilitative Evaluation

Concurrent with the toxicity testing, using excised human tissue in tissue-culture techniques, there is an active field evaluation program. Solicitations have been extended to a number of maxillofacial centers (Table 4). This portion of the project is intended to obtain the consensus among cosmetic prosthetic specialists or technicians in regard to the intrinsic coloring that is applied to the polydimethylsiloxane formulation described in Table 5. For the simplest possible formulation of the pigmentation, the nearest match to the red hemoglobin is achieved by means of an organic pigment and the match to the yellow carotene is achieved by means of pure yellow iron oxide. (To accommodate specialists accustomed to employing red and blue flock, these have also been prepared and sent out for field evaluation.)

TABLE 4.—*Summary of Extramural Participants in PMDS Prosthesis Evaluation Period: Jan. 1 to Dec. 31, 1977*

Prosthetic Center (Hospital)	Number of patients	Number of compositions	Number of prostheses
Veterans Administration, New York	9	5	26
Memorial Hospital, New York	6	4	18
Temple University School of Dentistry, Philadelphia, Pa.	3	3	12
Duke University, Durham, N.C.	1	4	4
(Private practice) Kantor	1	4	4
Cracow Medical Academy	4	3	14
Pending — solicited to participate:			
M.D. Anderson Tumor Institute, Houston, Texas	4 allotted	4	16
Mayo Clinic, Rochester, Minn.	4 allotted	4	16
Zoller Clinic, Chicago, Ill.	4 allotted	4	16

TABLE 5.—*Base PDMS Prepolymer-Oligomer (80/20) Composition with Intrinsic Pigmentation*

		Weight	
		Grams	Parts (%)
(a)	Prepolymer (gum stock)	16.0	(80.0)
	General Electric SE-4524U or Dow Corning MDX 44514		
(b)	Oligomer	4.0	(20.0)
	Dow Corning Silicone Fluid 200 or General Electric Equivalent		
(c)	Pigments (from 100X Concentrate)	0.2	0.1 0.05[a]
	Pure Yellow Oxide (Pfizer) 0.375		
	Pure Titanium Dioxide (DuPont) 2.00		
	Red Flock (Claremont) 2.50		
	Blue Flock (Claremont) (Varied preferences)		
(d)	Total	20.2	(100)

[a]Progressive intensities

During the past year 699 prostheses have been made in the simple and inexpensive dental stone molds (9) which can be used more than 40 times within the prescribed thermal range (100 deg to 120 deg C) of the polymerization (curing) conditions for the polysiloxane elastomer fabrication.

The field evaluation program commenced in April 1977, and to date there have been no reported deficiencies. This experience is in line with the experience in our own Maxillofacial Prosthetic Center as far back as 3 years, using the polydimethylsiloxane prepared according to the formulation indicated in Table 5. The participants are expected to return unserviceable prostheses for chemical, physical, and microbial inspection and evaluation.

Product Development

Fundamental to the priority efforts of toxicity testing for safety, and field evaluation for performance, has been the indispensible product development portion of the project with its dependent programs of fabrication technique and pigmentation of the fabricated prosthesis. The principal feature of the polydimethylsiloxane prosthesis formulation is the use of a prepolymer (usually referred to as the gum stock) to which is added an oligomer to lower the modulus to more nearly approximate that of living tissue in the sense of the stress-strain profile or the stress-elongation response (10). From the standpoint of polymer mechanisms and kinetics, this aspect of polymer science has not been accorded any basic investigation of what happens when process variables, with different free-radical catalysts, are imposed to convert the prepolymer into a well-characterized elastomer.

Table 6 illustrates a typical case in which these variables have a pronounced effect on the tensile characteristics of the formulation indicated in Table 5, with an interpretation of the mechanisms that are believed to be involved. Applying a novel correlation of the net elongation after polymerization, with the two free-radical catalysts benzoyl peroxide and 2,4-dichlorobenzoyl peroxide (designated BZPO and 2,4-DCBP, respectively) it becomes apparent that raw materials from a single manufacturer of silicone materials can acquire entirely different sets of tensile properties. It is on this kind of basic information that the eventual specifications for effectiveness of the prosthesis as a medical device will have to be based.

At present, the fabricating conditions are restricted to the temperature and time conditions indicated in Table 6. The program will require a reasonable exploration of the limits of these conditions. On the one hand this may supply the data to identify excessive application of the polymerization conditions, excessive use of catalysts, and so on, that can crop up unsuspectedly and thereby fail to provide the quality of performance and possibly compromise the safety that could be evident in the tissue toxicity tests. On the other hand, insufficient application of the polymerization condi-

TABLE 6.—*Comparison of BZPO and 2,4-DCBP using SE 4524 Prepolymer*

Formulation: Prepolymer — 16 grams (80 parts)
Oligomer — 4 grams (20 parts)
Polymerization 100° C for 2 hours (curing)

Code notebook reference	Catalyst	Amount (grams)	Tensile constants			
			Modulus (lb/sq in) (M)	Strength (lb/sq in) (S)	Elongation (%)	S/M quotient
L-124-27-A	BZPO	0.05	80.10	210.5	649.7	2.63
L-124-17-A	2,4-DCBP	0.05	32.66	128.5	1270	3.93
L-124-27-B	BZPO	0.10	129.5	251.3	426.9	1.94
L-124-17-B	2,4-DCBP	0.10	54.77	313.9	1141	5.73
L-124-27-C	BZPO	0.20	203.0	261.5	259.1	1.29
L-124-17-C	2,4-DCBP	0.20	115.1	568.8	836.2	4.94

To convert to metric system: _____ lb/sq in × 0.07037 = _____ kg/cm^2

Possible mechanistic interpretation:
Chain lengthening related to increase in elongation
Chain branching related to decrease in elongation and decrease in modulus
Chain cross-linking related to increase in modulus and increase in stress at failure

tions may give prostheses that would fail to meet the expected performance, and especially durability.

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Permanently Attached Artifical Limbs

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Introduction

Attempts to bring a skeletal extension out through the skin, in order to develop a permanently attached artificial limb, have gone through a variety of methods for bone attachment. The tibia of spanish goats has served as the animal model. We have previously reported our early attempts to use intramedullary rods, supracortical and supraperiosteal devices. All of these had a common denominator that caused them to fail: this common denominator was restricted bone circulation leading to distal diaphyseal necrosis.

Intramedullary Approaches

The early intramedullary rods necessitated counterboring the intramedullary canal, thereby destroying the nutrient artery. Our attention had subsequently been drawn to Dr. Frederick W. Rhinelander's work, in which he describes the bone's circulation as being from the central nutrient arteries of long bones out to the periphery of the cortex. This accounts for perhaps 3/4 of the bone's total circulation with the remainder being supplied via the periosteum.

Having gained this much insight, attempts were then directed toward making a bony attachment without disturbing the intramedullary canal. However, these methods (supracortical and supraperiosteal) were evidently causing local artery damage and venous occlusion. Although the resulting necrosis did not approach that noted using intramedullary reamers, there was still necrosis of the

distal 1-1½cm of the tibial shaft.

After discussing this problem with Dr. Rhinelander, we fabricated a prosthesis utilizing a self-broaching intramedullary Schneider nail. Theoretically, the area between the flutes allows room for retaining the intramedullary vascular channels. In order to increase the area between the flutes, we redesigned the nail to one which is trifluted, rather than quadrafluted. The pedestal remains very much the same as the supraperiosteal cup, which has three lugs penetrating the skin in areas of a uniaxial force field.

It was found rather early that flutes having a diameter large enough to stabilize the intramedullary nail were too large to be seated with a single pass with a broach. Attempts to use the self-broaching teeth invariably shattered the somewhat brittle shaft of the goat tibia. Step broaches of increasing diameter were fabricated and used in the last two attempts with excellent results.

Although the pilot model (based on the original quadrafluted Schneider nail) was successfully placed in a goat, no attempt had been made to alter the highly polished stainless steel surface to provide for bony ingrowth (Fig. 14). The pedestal and lugs were

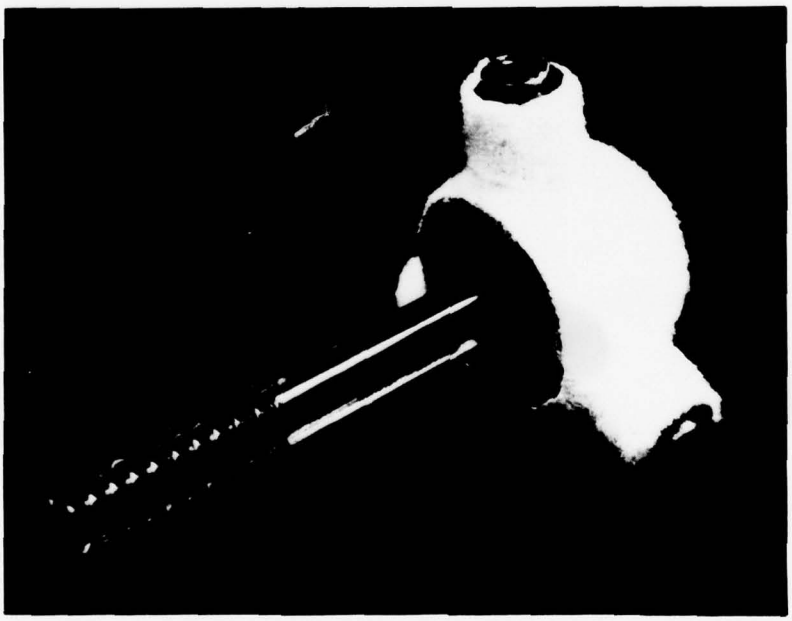


FIGURE 14.—One end of a Schneider nail has been affixed to a trilugged stainless steel pedestal. The pedestal and lugs have been coated with nylon velour for the skin-interfacing requirements. The surface of the nail remains unaltered in this prototype.

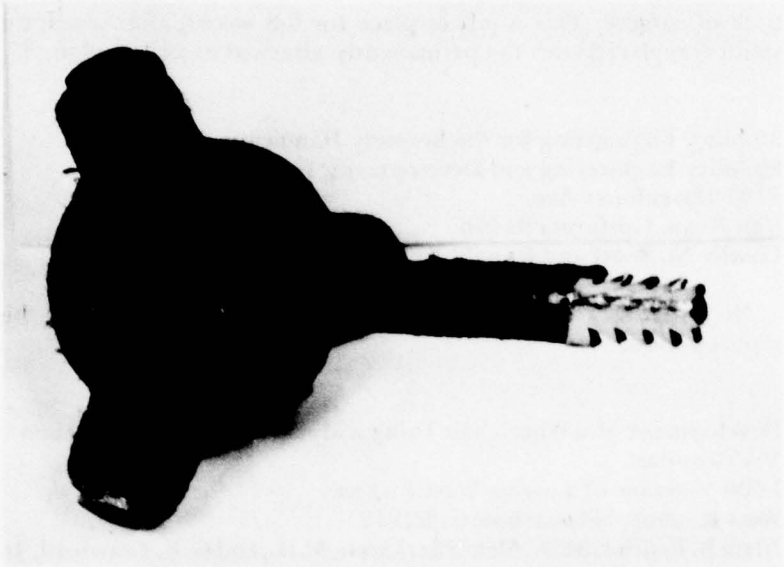


FIGURE 15.—Modified intramedullary nail having three, rather than four, flutes. Except for the broaching teeth, the entire device has been covered with Proplast®.

coated with nylon velour to provide for skin interfacing only. Ultimately, the intramedullary pin loosened and the animal had to be sacrificed. There was no evidence of bone necrosis either radiographically or grossly after 4 months' implantation.

Subsequent models (Fig. 15) have been sent to Dr. Charles Homsy of Houston, Texas, for coating with Proplast®. This material has gained wide acceptance as a tissue interfacing material and is being used clinically for maxillofacial reconstruction. Its skin interfacing properties are unknown at this time, but it appears to be on par with velour.

The above described approach seems a step closer to the ultimate for the following reasons:

1. It leaves the intramedullary and periosteal circulation pretty much intact;
2. The device is coated with a tissue interfacing material, which (it is hoped) will suffice for both bone and skin; and
3. Penetration of the skin utilizes the involuted approach, which should keep the skin from retracting away from the penetrating members.

Currently, we are applying a Thomas leg splint to the limb at the time of surgery. This is left in place for 6-8 weeks, after which the splint is replaced with the permanently attached exterior pylon.

Mobility Engineering for the Severely Handicapped
Mobility Engineering and Development, Inc. (MED)
7131 Havenhurst Ave.
Van Nuys, California 91406
Charles M. Scott and Ronald E. Prior, Ph. D.

No progress report was submitted by this contractor for this report period.

Development of a Wheelchair Using a Myoelectric Control System
VA Hospital
1400 Veterans of Foreign Wars Parkway
West Roxbury, Massachusetts 02132
Alain B. Rossier, M.D., Mehdi Sarkarati, M.D., and G.E. Crawford, Jr.

The object of this research is to develop a myoelectric control system that will operate, with barely perceptible twitches of surface muscles, in environments having levels of electrical interference that are typically encountered by one traveling in a wheelchair. The system is to be microprocessor controlled, and have electrical stimulation for feedback, both to avoid excessive muscular activity by the operator and to assist in the control function.

During the period from June 30 to December 31, 1977, development of the myoelectric portion of the equipment was completed, a preliminary breadboard of an electrical stimulation module was constructed, and writing of the microprocessor program started. The achievement of high myoelectric sensitivity simultaneously with a high degree of interference immunity was accomplished by use of a combination of the following techniques:

1. Totally shielding the amplifiers providing the first 70 db of gain in a small (5.8 X 2.6 X 0.9 cm) enclosure;
2. Placing this enclosure (with silver disc electrodes built into its surface) on the skin directly over the muscle to be monitored;
3. Using a shielded cable from this enclosure to the shielded postamplification and signal processing equipment;
4. Providing both a high common mode rejection ratio, and blocking the flow of common mode interference current, (by using an optical coupler in the signal path and a 29 MHz radio frequency

coupling system for the primary power source);

5. Using low-noise transistors (equivalent input noise voltage of 5 $nV/\sqrt{Hz}$) in a configuration that provides a low-system-noise figure;

6. Limiting the system bandwidth to include only frequencies of significant myoelectric energy; and

7. Extracting the information from the myoelectric signal in a manner that depends only upon the detection of minute bursts (rather than resolving differences in amplitude or extracting features of the wave form, both of which require myoelectric activity of greater amplitude and duration).

Preliminary tests of the myoelectric equipment have resulted in interference-free performance in typical laboratory and hospital environments.

The microprocessor program, partially written during the 6-month period covered by this report, will convert the coded outputs of the two myoelectric channels into motor control signals similar to those developed by a joystick assembly. It will also initiate the electrical stimulation mentioned above. In order to develop and evaluate the system without risk to the patients who volunteer to be experimental subjects, the motor control outputs will be further decoded to present the commands (forward, right, left, reverse, and stop) on a visual display, rather than actually activating the motors of a wheelchair.

The previously open consideration as whether to use random logic or a microprocessor was resolved in favor of the microprocessor. This facilitates the incorporation of such safety features as the insertion of a time delay if the operator generates a reverse command when the chair is traveling forward or a forward command when the chair is traveling in reverse, and the use of a decoding system that treats muscle spasms as stop commands. The decision to use a microprocessor also facilitates the flexibility to implement suggestions (for applications in addition to that of wheelchair operation) that resulted from the exposure of the myoelectric equipment to a group of people during its preliminary testing. These suggestions include using the system as an interface means for microprocessor-based TV games, and as a general purpose environmental control unit. Such suggestions could be implemented in future programs by changing the integrated circuit which holds the program for a specific application in memory and then connecting the peripheral equipment to be controlled.

Clinical and Physiological Evaluation of Seat Cushions for the Paralyzed

VA Hospital
Castle Point, New York 12511
Bok Y. Lee, M.D.

Veterans Administration Prosthetics Center
252 Seventh Avenue, New York, N.Y. 10001
Leon Bennett, M.A.E.

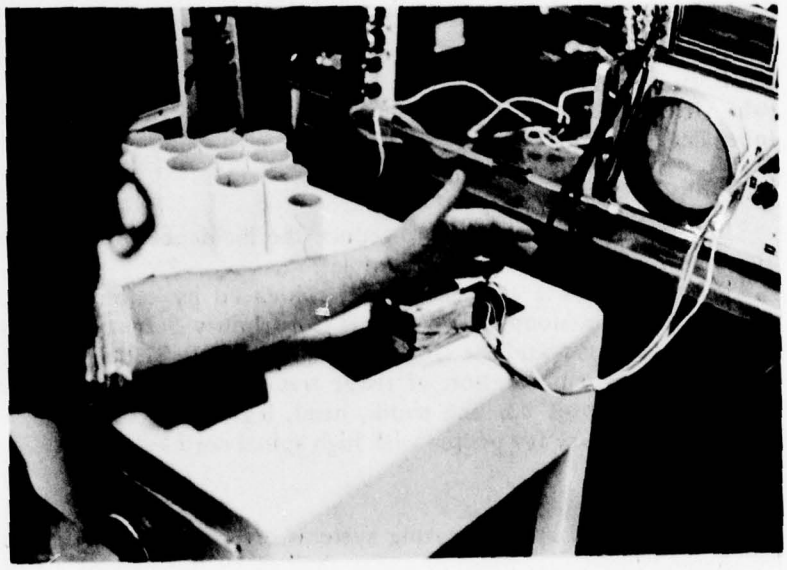
To design superior cushions for the paralyzed, it is first necessary to determine the significance of all loads in the seated condition. The importance of normal load (or pressure) in this connection is clear and a number of workers have detailed the seated pressure magnitude and resulting physiological consequences. *Tangential* load (or shear) has been relatively neglected. While most workers believe that shear effects are highly significant to the traumatic process, such beliefs appear intuitively based; no measures of seated shear magnitudes or effects are known to these investigators.

To assess shear load significance, a device has been constructed (Fig. 16) which *simultaneously* measures local blood flow and externally applied pressure and shear. With sufficient data, it should be possible to separate the independent effects of pressure and shear in reducing local blood flow.

Implicit in the experimental design is the belief that a dearth of local blood flow is a precursor to trauma—that factors tending to reduce local blood flow are "bad." While a dearth of local blood flow is certainly associated with trauma, such a dearth may constitute only a necessary condition and not a sufficient condition. For example, actual tissue failure owing to internal stresses may also be required to produce trauma. It is to be appreciated that in dealing with human volunteer subjects we are not in a position to create such failures. Thus we employ only the presence or absence of blood flow as an indicator of potential trauma.

The blood-flow monitoring device is a conventional optical plethysmograph, roughly 2 cm wide, capable of generating and monitoring red light reflected from the skin. Surrounding this device are three load pickups, of which two measure pressure and one, shear. All these devices are mounted flush with a heavy aluminum plate roughly the size of the palm of the hand.

Pressure and shear devices employ conventional SR-4 strain gages in a standard beam and column approach. The sensor design features small displacements (on the order of 0.001 in); large displacements, despite their attractive large signals, produce compli-



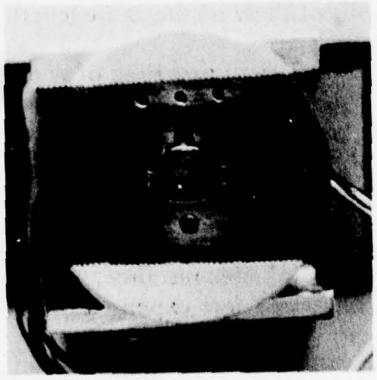


FIGURE 16.—Device for simultaneously measuring local blood flow and externally applied pressure and shear. A. Contact surface of the device shows optical plethysmograph at center; circular objects to *right and left are load pickups* for measuring pressure, and object below is load pickup for measuring shear. (Row of circular indentations are fastenings.) B. Measuring device in use.

ance difficulties in which the sensors act as displacement transducers rather than load cells.

The gathering of data has just started; we have no comment on the results, except to note that scatter is appreciable and that a statistical type of treatment will likely be necessary.

Seating Systems for Body Support and Prevention of Tissue Trauma

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Inder Perkash, M.D.

Purpose

This project is an attempt to reduce the incidence of decubitus ulcers in the spinal cord injured population.

The problem is a significant one, evidenced by estimates that one-half of admissions to VA Spinal Cord Injury Services are due to decubitus ulcers, and the cost per ulcer is $5,000–$10,000.

In addition to prevention of tissue trauma, seating systems can offer body support for the trunk, head, legs, and feet, which is especially necessary for people with high spinal cord lesions.

Concept

Custom-molded special seating systems are usually made either by shaping blocks of foam in a seat shell to fit the patient, or by taking a negative cast of the patient and then making a molded seat shell over a positive model. Both of these methods are lengthy in time and therefore expensive in cost.

In search of methods whereby more efficient provision of seating systems can be achieved, the concept of using pre-fabricated sections seemed a promising one and was selected to pursue in this project. With judicious selection of shapes and sizes, the seat, trunk, head and leg/foot sections can be put together clinically, on the spot, by using these off-the-shelf components.

If a significant percentage of patients could be fitted successfully in this manner, it would provide a valuable resource, allowing clinicians to fit patients faster, easier, and less expensively. Presumably, this would also allow more patients to have seating systems suited for their needs. There will always be certain patients who will need special attention and custom molding for proper fitting: the goal of this project is to reach the majority first.

Plan

The most essential part of a seating system is the seat itself, which distributes body weight of the individual over weight-bearing areas. Therefore, the project has started with the seat section.

The plan is, first, to design, fabricate and clinically evaluate the seat section. Then, presuming success (with redesign if necessary),

to work on other sections, adding one-by-one until a complete seating system is available and tested for use.

Comments

The project is progressing well thus far. Technical work in the design and fabrication of the seating system is being done at the Rehabilitation Engineering Center at Children's Hospital at Stanford, under the direction of Wallace Motloch, C.O. Trial use of the seating system and evaluation of results is being done at the VA Hospital, Palo Alto, under the supervision of Dr. Perkash and staff therapist Daryl Wright, O.T.R. The project will be continued in 1978.

Stump Stress Analysis

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Leon Bennett, M.A.E.

This project has been terminated. For the concluding report on this research, see BPR 10-26, Fall 1976, 257–285.

A follow-on effort has been initiated with Mr. A. Bennett Wilson, Jr.'s group at Moss Rehabilitation Hospital, Philadelphia. The new program will focus on the feasibility of forming an AK socket of thermoplastic materials. The greatest single problem, in prior development efforts using lamination concepts, has been in fatiguing of that material in proximity to the flexible brim. It is hoped that the use of fatigue-resistant materials, such as polypropylene, may resolve the difficult problem.

[a] As of April 1978, Mr. Bennett has joined the staff of the VAPC.

SENSORY AIDS

Edited by
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Electronics Engineer

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Clinical Application Study of Reading and Mobility Aids for the Blind

Eastern Blind Rehabilitation Center
VA Hospital
West Spring Street
West Haven, Connecticut 06516
Donald E. Garner, William R. De l'Aune, Ph. D., and Patricia D. Gadbaw

During this reporting period the Eastern Blind Rehabilitation Center hosted the First Annual Working Conference of Research Personnel stationed at VA Blind Rehabilitation Centers. In addition to the research staffs from the three VA Blind Centers, interested parties from other agencies attended. Information about current research projects was shared, and the meeting adjourned with a strong commitment for future cooperative studies between the centers.

Ms. Gadbaw hosted a seminar on Low Vision, in November 1977. The 2-week series of lectures and observations included topics such as the low-vision examination, geometric optics, physiological optics, eccentric fixation training, use of fresnel prisms for clients with reduced fields, perceptual problems in the visual and auditory systems, and psychological problems commonly encountered with the low-vision patient. This effort was in response to the many requests for information Ms. Gadbaw had received as chairperson of the Low Vision Interest Group of the New England Chapter of the American Association of Workers for the Blind.

[a] As of April 1978, Mr. Freiberger has joined the staff of the VAPC.

Dr. De l'Aune presented a series of lectures on the problems of the visually impaired with hearing loss, to a meeting concerned with Orientation and Mobility of the Visually Handicapped with Secondary Disabilities, held in Alexandria, Virginia, in October 1977. Other "secondary disabilities" covered at the meeting were psychological problems, diabetes, orthopedic disabilities, perceptual disorders, and advanced age. The applicability of guide dogs for use of the visually handicapped with secondary disabilities was discussed. A great deal of information was relayed to the EBRC staff upon his return.

A proposal to develop visual and auditory impairment simulation materials has been prepared. The purpose is to develop devices which are capable of simulating various basic types of auditory and visual impairment, and to generate manuals providing instruction in the use and limitations of these devices. The simulators are intended to assist in the education of the professional and lay people who need to gain a concept of functional impairment in the senses of vision and hearing. While most people can grasp the basic sensation of total blindness or total deafness with little difficulty, insight into the much more commonly encountered problems of partial vision or limited hearing is more difficult to gain. The simulators would be used to assist in explaining to family members the nature of the sensory loss specific to the veteran undergoing rehabilitation. In the course of professional training in rehabilitation, students would be exposed to such devices to learn more about different combinations of sensory defects. In the most rigorous application, these devices would provide researchers with the insights needed to design relevant evaluatory techniques and to develop and deploy more helpful devices to meet the needs of individuals with sensory needs which are at present ill-defined.

The project involves several stages. In the first, a group of consultants from various areas in the fields of vision and audition will be gathered, to define the types of sensory defects appropriate for simulation. In the course of this meeting, ways of implementing the simulation of these defects will be derived within tight fiscal constraints: it is felt that if such simulators are to be maximally useful, they should be priced within reach of educational institutions and rehabilitation centers. Several prototypes of the devices will be purchased by the VA and evaluated for acceptability by a second meeting of the consultants. During this time, manuals will be written and discussed. The prototypes will then be tested for validity of simulation by using monocularly or monaurally impaired subjects whenever possible. Descriptions of impairments by impaired

subjects will also be compared to the descriptions of unimpaired subjects using the simulators. A comparison of the performance of individuals with specific impairments with the performance of non-impaired subjects with the simulators, while involved with specific mobility, communicative, and avocational tasks, will be made on both the amounts and kinds of difficulties encountered. The effectiveness of the simulators as an educational tool would then be determined by distributing the devices to selected private agencies and schools for workers in the field of rehabilitation.

Many attempts at the fabrication of simulation systems have been made, but none are universally accepted. The "basement workshop" fabrication techniques, and the narrow focus of the devices, are believed to be the major reasons for this failure. It is hoped that this serious attempt will avoid those problems through the use of a diverse group of expert consultants, plus proper attention to engineering and design.

Preliminary experimentation, with blindfolded mobility instructors attempting to negotiate familiar indoor routes while wearing ear plugs and a hearing aid, has indicated that considerable insight into the problems of the elderly blind is possible. The minimal loss induced by the ear plugs (approximately 20 dB at the lower frequencies gradually rising to about 40 dB at 8 kHz), and the acoustic filtering effect of the hearing aid, caused considerable disorientation and anxiety in the blindfolded subjects. Marked postural changes were noted as well as difficulty in executing right angle turns. Increases in time required to complete various sections of the route were as much as five-fold when compared to simple blindfold travel. The instructors agreed that the experience was very constructive.

Work has resumed on the analysis and sensory training of acoustic cues present in ambient sound fields (for judgments of space), and for localization of sound sources. The ambient cues have been outlined in previous issues of the BPR, but the present work on localization is still largely in the design stage.

Probe microphones (Knowles Electronics) are placed in the ears of a "surrogate listener." The outputs from these microphones are recorded using a stereophonic tape deck, resulting in a binaural recording. The listener is seated in the center of a 12-ft circle facing an imaginary 12 o'clock. The experimenter walks around the circle, stops, and then asks "At what point am I?" After allowing 3 sec for a response, the experimenter gives the clock face position from which he spoke. When the tapes of such activities are played back through stereo headphones, most of the normally present binaural localization cues are reproduced.

By making tapes of graded difficulty and allowing the client to proceed at his own rate, it is felt that a programed instructional package in the important task of sound localization could be provided in a very efficient manner. More advanced tapes, with different sound effects reproduced from the various clock positions, are being considered for the purpose of combining sound identification with sound localization.

In a more complex situation, the probe microphones are being used to record the sounds heard by a client when he is at a traffic intersection. The microphones pick up the environmental sounds as well as the comments of the mobility instructor. With the aid of the tapes the client can review the lesson at some later time in a less anxiety-provoking situation. It is hoped that this technique will facilitate learning in some of the more anxious clients.

Clinical Application Study of Mobility Aids for the Blind

Central Rehabilitation Section for Visually Impaired and Blinded Veterans
VA Hospital
Hines, Illinois 60141
John D. Malamazian and Leicester W. Farmer

As this reporting period began, Mr. Leicester W. Farmer went to Colorado Springs, Colorado, for a visit at Kaman Sciences Corp. The purpose of the trip was to witness a field demonstration of a local high-resolution navigation system, which Kaman has been developing over the past few years. Mr. Farmer discussed with Mr. D. H. Bryce (special projects manager) and Mr. Randolph Wolf, (research scientist) the possible application of this system as an orientation and navigation aid for visually impaired persons.

A converted electric cart was used for the demonstration. The navigation system was built into the cart, enabling it to be controlled remotely. This system consists of three transmitters operating sequentially and establishing a phase-difference navigational grid. A microcomputer on board the vehicle converts the navigational information into guidance data and control commands for the steering servomechanism of the vehicle. This cart can travel with a high degree of accuracy along any path over which it has previously been.

The Kaman Sciences Corp. scientists believe that, although this positional measurement system has been used only with automotive vehicles, it is primarily only a matter of application to interface it

with a person so as to provide control information which could enable the visually impaired person to walk arbitrary paths within the navigational grid network.

A demonstration could be arranged to test the feasibility of interfacing this system with an individual. Either a blind or blindfolded sighted person could be used as a subject. The servo control signals that come out of the converted vehicle would be intercepted and converted to left and right signals. Details of how the signals would be presented, and whether they would be audible or vibratory, would have to be worked out and agreed upon. (Perhaps the frequency of those signals would depend upon the amplitude of the servo signals.) The vehicle would be driven manually ahead of or behind the subject, who would carry the receiving antennae on his person.

The demonstration would consist of recording a path or paths, via the vehicle, on the microcomputer tape system and on memory. When the cart finished recording the route(s) and returned to the starting point, the subject would start from that point, after having been connected into the loop, and would walk the path(s) that had been previously recorded by the electric vehicle within the navigational grid network. The subject should be able to travel the route(s) as accurately as did the vehicle.

The Kaman Sciences Corp. scientists feel that the technology is already available for miniaturizing the present system into a package approximating the size of an ordinary tape recorder, and if EPROMS (Erasable, Programmable, Read-Only Memories) are employed instead of cassettes, then the package could be considerably smaller, although more expensive. It was suggested that a feasibility demonstration could be conducted for as little as $2,000.

Mr. Farmer was invited to visit the Dysfunctioning Child Center at Michael Reese Hospital in Chicago, by Psychologist Margaret Creedon, to discuss with her the feasibility of using electronic travel aids in work with autistic children. Mrs. Creedon has done extensive work with autistic children and is one of the first persons to use simultaneous communication, which she describes as the combination of manually signed English and speech. It is an approach to working with nonverbal individuals who may or may not hear, who may not be able to produce speech or are developmentally delayed in speech and language, and who may have autistic type behaviors.

Since autistic children may be unsociable, self-abusive, spend considerable time in stimulating themselves, often ignore and do not explore their environment, and pay little attention to persons

around them, Mrs. Creedon wondered if the use of electronic travel aids might be employed to help make the children more aware of objects and walls in their paths and thereby afford them some protection, to reduce self stimulation, to get their attention, to increase their spatial awareness, to enhance their sociability, and to afford them some means of communication with their environment, however artificial it might be. Mr. Farmer and Mrs. Creedon used the Lindsay Russell Pathsounder and worked with the children on two occasions. Five children were evaluated with the device, and the audible and vibratory signals did succeed in getting their attention for varying periods of time. They all learned that the device did signal the presence of objects and/or their classmates in their travel paths or when they engaged in scanning. The results of the children's experiences were, of course, inconclusive but the children's responses did suggest that this may be an area in which an extensive study might be conducted to determine the applicability, if any, of electronic travel aids in training programs with autistic children or those with autistic type behaviors.

In October 1977, Drs. Andre G. Vacroux (dean's representative) and Kenneth W. Haag (assistant chairman of the Electrical Engineering Department) of Illinois Institute of Technology, Chicago, Ill., visited the Blind Rehabilitation Center at Hines to meet the chief, assistant chief, and research personnel and to discuss the establishment of a Rehabilitative Engineering Research and Development Center at Hines Hospital, and an affiliation with Illinois Institute of Technology. Dr. Haag returned to the Blind Center in November and December, 1977, to draft plans with Mr. Farmer to design a binaural wireless telemetry system, with two-way communication potential, for use with the Sonicguide.

Training with the electronic travel aids continues to be of primary interest at Hines, and although there was interruption of training procedures with both the Sonicguide (all Sonicguides were recalled during the first quarter to correct a power source problem) and the Laser Cane (the building in Bala Cynwyd in which the Laser Canes were manufactured was destroyed by fire in May, 1977), some five veterans completed training with the Laser Cane, and the Sonicguide. Training with the Laser Cane has been suspended at Hines until they are back in production.

Clinical Trials of Reading Machines for the Blind

Central Rehabilitation Section for Visually Impaired
and Blinded Veterans
VA Hospital, Hines, Illinois 60141
John D. Malamazian and Harvey Lauer

The work of this program is the clinical evaluation of electronic reading and other communication aids for the blind.

The major activity at present concerns the Kurzweil Reading Machine (KRM). The first of its kind, the machine automatically scans print using a minicomputer, a keyboard control and synthetic-speech output. The VA's first KRM was delivered here on June 1, 1977, at a cost of 50,000 dollars.

The machine is undergoing extensive testing as new computer software is provided. The researchers are regularly communicating with the manufacturer, Kurzweil Computer Products, Inc., regarding improvements. It was found that the KRM can read a variety of high-quality print styles with 97.2 percent character-recognition accuracy, adequate for many reading tasks. It is fairly easy to operate when the page format is simple, but requires skill when the format is complex and includes columns or illustrations. After several hours of experience, the output is intelligible to most people; some can immediately understand it. In its present form, the machine can handle carbon-ribbon typing, high-quality books and magazines, and well-duplicated print. It cannot usually read cloth-ribbon typing, newspapers, low-quality paperbacks, and poorly duplicated copies. It does very well with most common type styles —less well with ornate and italicized print.

Users of direct-translation reading aids (Optacon, Stereotoner) and Low-Vision Aids often use them to complement their use of the KRM for some tasks. It seems advisable to integrate a direct-translation output in a future model.

Manuals and familiarization recordings are being developed, and tested for efficacy as instructional aids in the use of the KRM. Mr. Lauer is also writing a short manual on the use of ancillary equipment (headsets, recorders, typewriters, etc.) with the KRM. Mr. Mowinski produced some training materials which included raised-line drawings of serif and italic letters. These are helpful to learners of all the reading aids.

Messrs. Farmer, Mowinski, and Lauer made a 40-minute demonstration video tape of the KRM and sent copies to the other two Blind Centers. This is to assist them in writing research proposals and planning for work with the Kurzweil Machines they are to

obtain in 1978.

All three researchers also participated in the First Annual Conference of Research Personnel at the Blind Rehabilitation Centers, held in West Haven, Connecticut, November 3-4, 1977. This conference provided a forum for increasing our awareness of the efforts of our colleagues at the Blind Rehabilitation Centers, and our cooperation with them.

During the first week in July 1977, Mr. Lauer attended the annual convention of the National Federation of the Blind in New Orleans. He served on the Research and Evaluation Committee of the organization, demonstrated the Kurzweil Machine, and conferred with employees of the manufacturer and with consumer and agency representatives.

The week of October 3-7, 1977, Mr. Lauer visited the Iowa Commission for the Blind. He conferred with evaluators of the KRM and worked with their machine for comparison purposes. He visited the agency and conferred with its staff regarding services and research objectives.

Clinical Application Study of Reading and Mobility Aids for the Blind

Western Blind Rehabilitation Center
VA Hospital, 3801 Miranda Avenue
Palo Alto, California 94304
J. Kenneth Wiley, Gregory L. Goodrich, Ph. D., Richard R. Bennett, and H. Stanley Paul

In November 1977 the staff of the WBRC moved from Building 205 at the Menlo Park Division into Building 48 at the Palo Alto Division, VAH, Palo Alto. Building 48 was specifically designed to house the WBRC and provides for an expanded patient population. The increase is from 18 to 30 beds with a proportionate increase in staff. The building also provides expanded and improved facilities for research, which will result in a broader range of research being conducted at the WBRC. Several new research projects are being planned. One of these, a cooperative study with the School of Optometry, University of California, Berkeley, will examine contrast sensitivity in relation to mobility by low vision students.

Mobility Aids and Training

The mobility followup has continued, with an additional 29 veterans visited in their home environments during this reporting

period. These bring the total number of veterans visited to 51. The followup, when completed, will include about 100 veterans, including 25 to 30 veterans trained in the use of electronic travel aids at the WBRC.

Three veterans were given electronic travel aid training between July 1 and December 31, 1977. One veteran was trained with the Pathsounder and one with the Mowat Sensor, and both were subsequently issued these aids. The remaining ETA candidate began training in December, 1977 with the Laser Cane and his training is still in progress.

Reading Aids and Training

The preliminary evaluation of the intelligibility of synthetic-speech reading machines was completed in late 1977. The evaluation utilized tape recorded material provided by Mauch Laboratories using the Cognodictor programing and a Votrax voice output. Thirty volunteers from the WBRC patient population participated in the study. Among the variables examined were reading speed, pitch, word length, and comprehension. The subject's age, education, Wechsler Adult Intelligence Scale (WAIS) Verbal IQ, and WAIS verbal subscale scores were also correlated with subject's performance. Rate of presentation (reading speed) and pitch were not significant variables. Subjects did exhibit significant performance improvements after a brief (30 to 45 min) exposure to synthetic-speech.

The correlation of the WAIS data with performance variables (word recognition and comprehension) suggests that such readily available and easily administered tests as the WAIS may be useful in selecting candidates for training with synthetic-speech reading machines and/or in defining remedial training areas to improve a subject's performance. These results are preliminary, and further work is planned to validate and expand upon them. The results of the preliminary evaluation have been reported to the VA Prosthetics Center.

Also during the reporting period, one service-connected veteran received Optacon training. The veteran plans to utilize the Optacon to assist him in some print reading tasks associated with his small business.

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Goodrich, G. L. and R. D. Quillman: CCTVs: Choices and Considerations. J. Vis. Impair. and Blindness (in press).
Goodrich, G. L. and R. D. Quillman: Eccentric Viewing. Paper read at the American Association of Workers for the Blind, Biennial Conference, Portland, Ore., July 1977.
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Quillman, R. D. and G. L. Goodrich: Eccentric Viewing: A Case Report. Long Cane News, 10(2):9-14, 1977.
Quillman, R. D.: Utilization of Telescopic Lenses in Low Vision Mobility. Long Cane News, 10(2):3-8, 1977.
Quillman, R. D.: Eccentric Viewing. Paper read at the American Academy of Optometry Annual Convention, Section on Low Vision, Birmingham, Alabama, December 1977.
Quillman, R. D.: Utilization of Telescopic Lenses in Low Vision Mobility. Paper read at the American Association of Workers for the Blind Biennial Convention, Portland, Oregon, July 1977.
Wiley, J. K., G. L. Goodrich, R. R. Bennett, and H. D. Paul: Clinical Application Study of Reading and Mobility Aids for the Blind. Bull. Prosth. Res., BPR 10-28, Fall 1977, 232-235.

Research on Audible Outputs of Reading Machines for the Blind

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New Haven, Connecticut 06510
Franklin S. Cooper, Ph. D., Andrea Levitt, Ignatius G. Mattingly, Ph. D., Patrick W. Nye, Ph. D., and Linda Shockey, Ph. D.

The objective of the research reported below is the improvement of the intelligibility and naturalness of speech produced by an automatic synthesis-by-rule system.

Synthesis Playback

Hardware and software arrangements for pulse-coded modulation (PCM) input and output to the PDP 11/45 computer have been completed. A computer terminal has been set up in a quiet booth, with two PCM output channels, a Tektronix 4010 keyboard and storage scope display unit, hard copy unit, headphones and tape recorder.

Software Synthesizer

The software synthesizer mentioned in BPR 10-28 has been further elaborated. The synthesizer consists of a noise generator, a glottal waveform generator, a vowel branch with five formants, and nasal and consonant branches each having one formant and

one antiformant, and a radiation and preemphasis filter.

Two alternative modes of glottal excitation are available. The first mode follows Fischer and Engebretsen (1) in using Rosenberg's (2) polynomial approximation of a glottal waveform. The proportions of the glottal cycle for which the glottal opening is increasing and decreasing are variables. In the other mode, the waveform is explicitly represented by 72 ordinate values, following Holmes (3). Both approaches give reasonable voice quality.

When glottal excitation and fricative excitation are both present, as in voiced fricatives, the input from the noise generator to the fricative branch is modulated by the glottal waveform, following Rabiner (4).

The synthesizer is programed as three FORTRAN subroutines: SYNSET, SYNTH, and SYNEND. SYNSET initializes a number of synthesizer variables, SYNTH computes the PCM values corresponding to a set of synthesizer parameter values representing five msec of speech, and SYNEND tidies up after PCM values for an entire utterance have been computed.

All the important variables (besides the dynamically varying parameter values) that determine the synthesizer output—the glottal opening variables, the amount of glottal modulation of fricative input, the bandwidths and frequencies of formants F4 and F5, various gain constants, the sampling rate—are specified in a block data file, SYNDAT, and can be changed by the user. Diagnostic options enable synthesis with a variable number of vowel formants and printout of intermediate stages in the calculation of a PCM value.

Direct Synthesis

SYNSET, SYNTH, and SYNEND are used both by SYLSYN, the synthesis-by-rule program, and by a new program, SYA, which enables synthesis from a parameter-value array determined directly by the user rather than by rule. A set of commands, each of which invokes an appropriate subroutine, allows the user to create a parameter-value array, display it either numerically or as a stylized spectrogram, edit it, file it and retrieve it, compute the corresponding PCM values, and produce an audio playout. To avoid undue proliferation of PCM files, the PCM values are written over previously computed values in a fixed workspace on the storage disk; a command enables transfer of values to a permanent PCM file if desired.

Research Synthesis by Rule

In SYLSYN, the synthesis-by-rule program, the rules are at present stated in a FORTRAN subroutine, RULES. Before computation of the parameter values for a syllable, RULES tests each of a series of rules to determine whether the phonetic description in the rule matches the phonetic description of the syllable. If a rule applies, values are assigned to one or more arguments of the parameter-value computation routine. This approach makes for reasonably fast computation, but has two serious disadvantages. Certain types of rule (for example, those that assign values to one or more arguments) are cumbersome to state in FORTRAN. And every revision of the rules requires not only editing and recompiling RULES, but also rebuilding the SYLSYN task—a time-consuming process. As an alternative, a rule-writing language has been devised that is convenient for the user, yet relatively simple in syntax. A compiler program will convert a statement of the rules in this language into object arrays that a SYLSYN subroutine can use to assign values to arguments as rapidly as possible. Thus revision of the rules will involve only editing, compilation, and reading in the new object arrays to SYLSYN. The conventions of the rule-writing language have been worked out and the assignment subroutine, RULRUN, has been written and debugged; it remains to program the compiler.

Rule Development

Rule specifications for [w] and [y] in initial and intervocalic position have been prepared and tested. The phonetic facts here are well known; the chief difficulty has been to get rid of a transient noise that appeared in the acoustic record in utterances such as [aya] as F2 and F3 attained their maximum values. This transient resulted from the very rapid formant movement that the synthesis algorithm causes the synthesizer to produce near the end of a transition between two widely differing frequency values when the time-constant is fairly large. Choosing a considerably smaller value for this constant and a correspondingly greater value for the constant that controls transition duration, seems to take care of the problem without loss of the required phonetic value.

Temporal Patterns of Syllables

A further experiment on the temporal patterns of syllables has been carried out, paralleling those described in BPR 10-28. In this

experiment each of the disyllables

[ey fɔ^{r}], [pey fɔ^{r}], [pleyfɔ^{r}], [eytfɔ^{r}],
[peytfɔ^{r}], [pleytfɔ^{r}], [eyntfɔ^{r}], [peyntfɔ^{r}],
[pleyntfɔ^{r}], [eydfɔ^{r}], [peydfɔ^{r}], [pleydfɔ^{r}],
[eyndfɔ^{r}], [peyndfɔ^{r}], [pleyndfɔ^{r}]

was spoken in the frame: "She was seen on _____Street by her mother" 30 times by one of the same speakers used for the earlier experiments. The initial syllables of these disyllables were chosen to allow comparison with the monosyllables used in the earlier experiments. The second syllable of each disyllable was always

[-fɔ^{r}].

The measurements revealed patterns that were, in general, similar to those for the corresponding monosyllabic utterances. Thus initial [l] lengthened the first syllable very little; initial [p] and final [t] lengthened it by a moderate amount; medial [n] and medial [d] lengthened it considerably; and final [nd] lengthened it a very great deal. Initial [p] shortened the second syllable slightly; initial [l] had no effect; medial [t] and [d] lengthened the second syllable somewhat; medial [n], and especially medial [nd], produced a decided lengthening of the second syllable.

Segmental Cues

The study of consonant transitions before low unrounded vowels, previously discussed in BPR 10-28, has been completed.

The purpose of these experiments has been to study, for a quite narrow range of vowels, the interaction of the steady-state frequency of F2 and the onset frequencies for the F2 and F3 transitions in the perception of the /b-d/ and /d-g/ boundaries. As reported in BPR 10-28, four synthetic vowels 200 msec in length, with steady-state values of 840 Hz for F1, 1200 Hz, 1400 Hz, 1680 Hz, and 2100 Hz for F2, and 2700 Hz for F3, formed the basis for the experimental stimuli. Without consonantal transitions, these vowels are heard as variants of [a]. Four stop-vowel continua were created by imposing a series of initial transitions 40 msec in length on each vowel. For F1, the frequency at the onset of the transition was always 200 Hz; for F2, the onset frequency was varied from 850 to 2650 in 10 steps, and for F3, the onset frequency was 2700 Hz, equal to the steady-state frequency.

These stimuli were used in a pilot experiment in which 9 subjects were asked to label the stimuli as beginning with /b/, /d/ or /g/. For the F2 steady-state frequencies given above, the /b-d/ boundary estimates obtained were 1475 Hz, 1400 Hz, 1600 Hz, and 1900 Hz, respectively; the /d-g/ boundary estimates were 2100 Hz, 2200 Hz, 2100 Hz, and 2175 Hz, respectively.

After some additional informal testing, the /b-d/ estimates were revised to 1250 Hz, 1350 Hz, 1650 Hz, and 1650 Hz, respectively. It seemed desirable to make more refined estimates of the /d-g/ boundaries, so a further pilot experiment was conducted with six subjects, in which the F2 onset was varied in nine 100 Hz steps centering on the /d-g/ boundary estimates obtained in the first experiment. The resulting boundary estimates corresponding to the stated F2 steady-state frequencies were 2300 Hz, 2200 Hz, 2150 Hz and 2200 Hz, respectively.

For each vowel, two new labeling tests were then prepared in which the F2 onset frequency was varied in five 100 Hz steps centering on the boundary estimate for /b-d/ or /d-g/, while F3 was varied in seven 200 Hz steps centering on 2700 Hz. There were thus eight tests, each of which included 35 different stimuli. Each stimulus in a test occurred eight times. These tests were given to 12 subjects.

The responses for /b-d/ shows a systematic relationship among the three variables. In general, lower onset frequencies (i.e., more negative transitions) for either F2 or F3 yield /b/ responses rather than /d/ responses. The boundary value for either of the two onsets increases as the boundary value for the other decreases, so that the more negative the F3 transition is, the less negative the F2 transition need be to yield a /b/ response. Increasing the steady-state frequency of F2 displaces the boundary toward higher F2 and F3 onset frequencies.

The /d-g/ data are somewhat more complex. In general, higher onset frequencies for F2 and lower onset frequencies for F3 yield /g/ responses rather than /d/ responses. The boundary values for the two onsets increase together, so that the more negative the F3 transition is, the less positive the F2 transition need be to produce a /g/ response. With an increase in the F2 steady-state frequency, the boundary value is at first displaced toward lower F2 onset frequencies and higher F3 onset frequencies. But the displacement is not entirely consistent, and in the case of the higher F2 steady state (2100 Hz) the direction of displacement is reversed: the F2 boundary values are higher and the F3 boundary values are lower than for the lowest F2 steady state (1680 Hz). This reversal reflects the sharp difference in the F2 and F3 loci for velars before front versus

back vowels.

These results are quite consistent with the results of earlier studies of the F2 and F3 transitions as cues to place (Liberman, Delattre, Cooper and Gerstman (5), Delattre, Liberman and Cooper (6), Harris and Hoffman (7), but they explore in somewhat more detail the part of the vowel space associated with the velar locus difference.

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Development of a Hearing-Aid System with Independently Adjustable Subranges of Its Spectrum Using Microprocessor Hardware

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The work, during this report's 6-month period from July 1 to December 31, 1977, has centered on various aspects of introducing

systems engineering, and digital, methods and approaches to audiology and to audiology laboratories.

Specifically, we have completed or almost completed some hardware designed earlier, such as an overshoot distortion generator with independent controls on overshoot rate, frequency, and gain. A harmonic distortion generator with independent controls on distortion level and on frequency is nearing completion. Both of these are to undergo clinical tests.

Work on utilizing our design of an independently controlled staircase array of bandpass digital filters has also continued. Here we have found that, with the present speed of microprocessors, one cannot yet obtain an adjustable microprocessor array for processing of speech above 1000 Hz. However, with the rapid progress in the microprocessor industry, this situation should be overcome in the near future. We have tested our design successfully up to 1000 Hz, using the Intel 8 Mod 80 microprocessor system at our laboratory at Colorado State University.

We have also started work on designing a laboratory-scale test unit based on the independently adjustable array of digital bandpass filters discussed above. Such a test device is to serve the audiologist in accurately measuring the hearing spectrum of a patient. The system is to be fully computer-controlled. Since it is not to be a patient-carried device, some of the speed problems of the previous design can be overcome via a combination of analog and digital elements.

The Development of Improved Techniques for the Analysis of Hearing-Aid Performance

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Variability Among Samples of Hearing-Aid Models

Gain variability as a function of frequency, among samples of hearing-aid models, was examined for a group of hearing aids purchased by the Veterans Administration for distribution to audiology clinics nationwide. A total of 27 models (25 samples each)

from different power categories (mild to strong) and type (body, behind-the-ear, and eyeglass) were tested on a Bruel & Kjaer hearing-aid-test system using the 2 cm^3 coupler with all hearing-aid volume controls set to full-on.

Measures of central tendency and dispersion, including means, standard deviations, and performance ranges for gain as a function of frequency were obtained.

Results indicated that, although the degree of variability was generally acceptable, large individual differences do exist among samples of a model. Variability in gain was found to be greater at the low and high ends of the frequency range. Some manufacturers tended to have good product uniformity overall, while others exhibited varying degrees of product uniformity for their models. Hearing aids of a particular power category or type did not show greater amounts of variability.

Since one cannot predict the consistency of performance among samples of a model, it is strongly suggested that patients receive the hearing aid with which they are tested during the hearing-aid evaluation. Patients evaluated with a clinic's stock hearing aid should return to the clinic for followup evaluation with their own aids.

Hearing-Aid Quality Judgments

One of the major aims has been to investigate the sensitivity of quality judgments in normal and impaired ears. In general, the purpose was to determine the extent to which such judgments might be useful as supplementary or exclusive information in the selection of a hearing aid for an individual patient. To this end, we postulated four experimental questions: (i) is the intrasubject test-retest reliability of quality judgments of hearing-aid-processed stimuli sufficiently high to demonstrate acceptability for use in clinical situations? (ii) are preferences for different hearing aids on a quality judgment task correlated when the hearing-aid-processed stimulus materials consist of a male voice, female voice, or music? (iii) do normal-hearing and hearing-impaired listeners, as listener groups, yield preference judgments that are correlated with one another? (iv) within a given group of subjects, normal or hearing-impaired, are preference judgments similar from one individual listener to another?

Ten normal listeners and ten listeners with mild-to-moderate high-frequency sensorineural hearing loss were administered a paired-comparison paradigm designed to elicit preference among hearing aids when male speech, female speech, and music were processed by five different instruments. Results revealed test-retest reliability coefficients ranging from 0.86 to 0.35 across the three

stimulus conditions and two subject groups. Reliability was notably higher within both groups for the male speech condition and in normal listeners for the female speech condition. An analysis of subjects' ability to repeat their first-preferred choices was performed. First-preference judgments of individual listeners revealed good reliability for the male speech condition, and a tendency toward progressively reduced reliability on the female speech and music conditions, respectively. This trend was in keeping with that revealed by the overall data. Test-retest reliability was, in general, better for the normal-hearing than for the hearing-impaired group; the latter group demonstrated a higher number of tied first preferences than did the former.

When test and retest data were combined, preferences assigned for any one of the three stimuli were found to be positively correlated with those assigned for each of the other two stimuli. Preferences of the hearing-impaired group were statistically correlated with preferences of the normal listeners, when results were pooled across test sessions and stimulus materials. Rankings derived from the preferences of individual subjects, within the separate groups, were highly related to those of the other subjects within the *respective group*.

These results indicate that paired-comparison quality preferences of hearing-aid-processed speech, particularly the male voice, are adequately reliable for clinical use. The quality judgment task examined here was found to reflect a reasonably high degree of sensitivity to differences among hearing aids, although the presence of a number of tied preferences in the individual test-retest data fails to support fuily the claim of Jeffers (2) that quality rankings are "amazingly definite and unambiguous."

These findings reveal generally high reliability and relatively strong differentiating power of paired-comparison quality judgments and also suggest that quality rankings of hearing aids are virtually identical among individuals with high-frequency sensorineural hearing loss of mild-to-moderate degree. Of course, excellent hearing in the low frequencies by this group would tend to make their judgments of quality similar. The results, therefore, should not be generalized to individuals demonstrating more severe hearing impairments than those exhibited by the subjects in this study.

Listener-Assessed Intelligibility of Aided Speech

In a study related to that on quality judgments, the ability of listeners to assess subjectively the relative intelligibility of connected discourse was investigated. Here, the aim was to determine

whether the intelligibility of speech, as processed via hearing aids, can be evaluated accurately and reliably by the use of listener-based criteria, as opposed to criteria determined by the experimenter (i.e., percentage of words correctly repeated).

Discourse, spoken by a male talker with General American dialect, was processed by five hearing aids under conditions of quiet and a background of multitalker babble. Hearing-aid-processed Revised Central Institute for the Deaf Sentences, spoken by the same male talker and embedded in the same multitalker background, were used as stimuli in establishing criterion intelligibility performance. All stimuli were tape recorded and delivered via monaural earphone to 90 normal listeners.

Test-retest results revealed a reliability coefficient of .94 on the paired-comparison condition in quiet, and a coefficient of .65 on the paired-comparison, babble, condition. A low positive relationship was observed between responses on the two subjective tasks. An almost negligible correlation was found between subjective preferences on these individual conditions and performance on the sentence task. The latter result was attributed in part to the inability of the Revised Central Institute for the Deaf Sentences to differentiate strongly or consistently among hearing aids.

On the basis of this study and previous research (1) it is suggested that listeners may be presumed to evaluate their aided success in everyday listening situations on the basis of factors untapped by clinical quantification of speech intelligibility. The implication is that audiologists should begin research efforts to examine the relationship between aided clinical measurements of listener-assessed speech intelligibility and success with hearing aids in real-life situations.

Investigation of Signal/Noise Ratio Measurement

Electroacoustic measurements of hearing aids have traditionally been designed to satisfy requirements for simplicity, reliability, and reproducibility among test locations. Furthermore, they have been modeled largely after tests used to evaluate high fidelity electronic equipment. The VA's extensive hearing-aid procurement and distribution system requires a continual examination of the relevance of such measurements and the development of more advanced measures. The Auditory Research Laboratory serves in a consultant capacity to the hearing-aid program. Part of the current effort is to explore and develop measurement procedures which may improve the precision and clinical significance of the electroacoustic comparisons.

One such development is a test that introduces both noise and a tone to the hearing aid. By incorporating a filter arrangement which could be used to either reject the tone (passing only the noise) or reject the noise (passing only the tone), we were able to measure the signal-to-noise ratio (S/N) of the hearing aid more meaningfully. S/N ratio tests in hearing aids are normally a quantification of the quiescent noise of the instrument. These data relate to the "noisiness" of the aid in quiet conditions but do not describe the ratio of a particular signal to the background noise when both are simultaneously amplified through the entire hearing-aid system.

Our original arrangement produces the output values for the signal and the noise on a single recording. Using tones which were varied in level between 60 and 75 dB SPL concurrently with 55 dB of speech spectrum noise, the S/N ratio was examined for dynamic amplitude conditions. These measurements provided information about the amount of dynamic range alteration the aid introduced, as well as the S/N values at specific frequencies. For example, many aids with automatic gain control (AGC) circuits would typically reduce the 15 dB level change to less than 5 dB at the output. At some frequencies we observed 1 or 2 dB of expansion of the signal. This was true for both compression and non-compression aids.

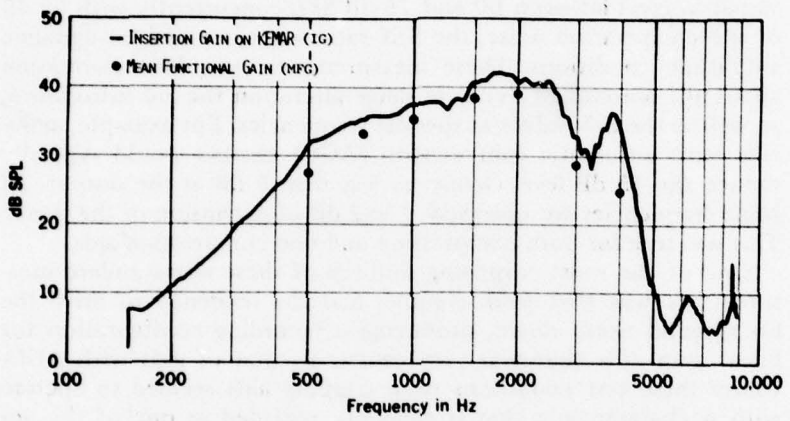
One of the most surprising findings of these non-standard measurements was that peak clipping had the tendency to drive the background noise down, producing a recording configuration for linear gain aids that was very similar to that of aids with AGC. Under these test conditions peak clipping aids seemed to operate with a characteristic that is generally regarded as one of the advantages of AGC aids. Several modifications of the measurement protocol are currently being investigated.

The Relation of Measurements on Kemar to Behavioral Performance

It was the purpose of this investigation to obtain functional gain measures on sensorineurally-impaired subjects and relate those measures to hearing-aid insertion gain. Functional gain is defined as the difference between aided pure tone sound field thresholds and unaided pure tone sound field thresholds. Insertion gain is the sound pressure at the coupler microphone with the hearing aid in place on KEMAR less the pressure which would exist at the coupler microphone with no hearing aid in place.

The subjects were 10 patients of the Audiology and Speech Pathology Service, VAH, Washington, D.C., with sensorineural hearing losses in the moderate to moderately-severe category. The Grason-Stadler Audiometer Model 1702 was used for the measures of functional gain. Bruel & Kjaer and associated test equipment was

used for insertion gain measures on KEMAR. The insertion gain of a moderate power over-the-ear hearing aid was measured on KEMAR in the anechoic chamber. The volume control position was full-on for this measurement. With this same hearing aid, aided and unaided threshold measurements using interrupted pure-tone stimuli were made with the opposite ear occluded. The volume control position was identical for both procedures. Fully occluding earmolds were used on the manikin and the subjects. For most frequencies there is a 2 dB difference between mean functional gain and insertion gain on KEMAR (Fig. 17). The range of responses was high, especially for the higher frequencies.



(BELOW) DIFFERENCE, IN DECIBELS, BETWEEN IG AND MFG AT VARIOUS FREQUENCY LEVELS

	500	750	1000	1500	2000	3000	4000
MEAN	4	2	2	2	2	4	10
RANGE	14	14	6	18	18	24	30

FIGURE 17.—Mean functional gain and insertional gain on KEMAR.

Many factors can contribute to lack of agreement between insertion gain and functional gain:

1. Subject's clothing;
2. Tubing dimensions;
3. Body size and shape;
4. Position of the hearing aid on the subject's head; and
5. Earmold differences and insertion depth.

Because of the great interest of clinicians and engineers in insertion gain and functional gain, research in this area is continuing.

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Compression Amplification and Speech Intelligibility in Noise—A Final Report

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This study was designed to investigate the influence of various methods of compression amplification on speech intelligibility, and to evaluate the effectiveness of compression amplification in reducing tolerance problems for loud sounds. The three types of compression amplification systems under study were the Automatic Volume Control (AVC), the fixed ratio (2 to 1), and the variable ratio compression. Comparisons were also made between the compression and the conventional linear amplification systems.

A wearable master hearing aid with switch-selectable controls was designed and built by a hearing aid manufacturer for this study. The hearing aid was housed in a pocket-size package which was connected via a miniature cable to a post-auricular module. This module contains a forward-facing omnidirectional microphone and a receiver. The pocket package houses the battery, volume control, electronic circuitry and selector switches. An 18-in cable was used to connect the two units. The frequency response of the master aid was designed to approximate that of a typical commercial hearing aid. Measurements of the electro-acoustic characteristics of the master aid were obtained using the ANSI standard (S3.22-1976). Furthermore, the amplitude non-linearities of the four systems were measured using three different distortion measurements: harmonic, difference-frequency, and intermodulation distortion.

Twenty-four subjects with mild-to-moderate bilateral sensorineural hearing loss were included. The master aid was worn in the aided ear and the test words (Northwestern University No. 6) were presented at 70 and 85 dB SPL with a S/N of 6 dB calibrated to a point representing the middle of the subject's head.

The compression amplification system was found to improve the listener's discrimination ability in noise. Especially at the loud speech level, the observed difference reached 24 percent.

Among the three types of compression amplification, the 2 to 1 fixed ratio compression was found to exhibit the best performance at both presentation levels.

Furthermore, the compression amplification system was found to increase the aided dynamic range and thus effectively reduce the tolerance problem for patients with sensorineural hearing loss. High level of DF (Difference-Frequency) and IM (Intermodulation) distortions, along with reduced aided dynamic range, were the likely factors that caused the decreased discrimination scores for the linear amplification system.

Development and Evaluation of a New Artificial Larynx

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At present, there are approximately 30,000 laryngectomees in the United States. At least 9,000 new laryngectomees are discovered each year. However, due to a 50 percent attrition rate the general number of laryngectomees within the population remains constant.

There are several methods of acquiring oral speech communication available to the laryngectomized individual: these include esophageal speech, air bypass, and pneumatic and electric larynxes. There are problems inherent with all of these methods and/or devices.

The goal of the proposed program of research is to develop a neck vibration device that (i) is cosmetically pleasing, (ii) has effective contact over a wide range of post-surgical anatomical structures, (iii) can be fitted to the neck for extended periods of time, (iv) has a choice of activation by either resistive respiratory pressure, muscle action potential, or hand switch, (v) will be highly intelligible over a wide range of acoustic environments, and (vi) will be driven by a waveform similar to the natural laryngeal tone.

This research program will seek major advances in the reduction of input impedances and the coupling between the device (to be developed) and neck tissue. This will, in effect, provide an almost direct coupling to the air in the vocal tract. The approach taken is analogous to the coincident frequency phenomenon in vibrating panels. Further, the type of neck-mounted collar devised will eliminate masking transmission and will reduce power requirements.

NOTES AND NEWS

VETERANS ADMINISTRATION REHABILITATIVE ENGINEERING REFERENCE COLLECTION

The primary mission of the Office of Technology Transfer, Rehabilitative Engineering Research and Development Service, is to expedite the transfer of research results into clinical practice; this will include the dissemination of information on new devices and techniques developed in the rehabilitative engineering program. One of the means used by OTT to achieve this goal is a unique reference collection situated in New York.

This collection was begun more than 25 years ago by the Research and Development Division of the VA Prosthetic and Sensory Aids Service, Department of Medicine and Surgery, which in 1973 became the Research Center for Prosthetics, from which OTT has recently evolved. Thus the collection's management has been continuous despite name changes.

The resulting collection includes both formal and informal publications, unpublished information, patents, reports of research projects, progress reports, and audio-visual materials. There is also an extensive collection of handout materials. Today the OTT has probably the largest collection of its kind in the world and OTT is still in the process of acquiring information and materials in the related fields. The present holdings include 2,500 books, 135 periodicals (including back issues of some journals since the collection was instituted), 900 technical reports to VA or other agencies, 12,500 reprints and copies of papers, 7,000 patents, 80 films and 22 videocassettes, all dealing with various aspects of the field of rehabilitative engineering. The collection is valuable for both retrospective research and modern studies. This collection has been and is currently used as a source of reference for a highly specialized clientele whose interests are in prosthetics, orthotics, spinal-cord-injury, automotive adaptive equipment, and sensory aids. The last category includes material concerning the hearing impaired and the deaf, the visually impaired and the blind, and, those with speech defects.

This reference collection is available for use by all individuals in the medical or allied health and engineering professions, on

the premises, through the mail, or by phone. Some materials may be borrowed (through interlibrary loan service to individual institutions and rehabilitation centers) for clinical research purposes. Photocopies of specific articles are provided on request for personal research and study. There is also a limited supply of pamphlets, booklets, reports, suggested references and various other types of materials: appropriate documents of specific interest are available free to visitors and are distributed at no cost to rehabilitation centers throughout the world in response to requests for information on clearly defined topics.

For additional information on the collection, or specific inquiries and service, write to: Ms. Lily W. Hom, Rehabilitative Engineering Reference Collection, Office of Technology Transfer, Rehabilitative Engineering Research and Development Service, Veterans Administration, 252 Seventh Avenue, New York, N.Y. 10001.

AEMB ELECTS NEW OFFICERS FOR 1978-79

The Alliance for Engineering in Medicine and Biology has elected the following new officers for 1978-79: President, Edward J. Hinman, M.D., Assistant Surgeon General and Director, Division of Hospitals and Clinics, U.S. Public Health Service, College Park, Md.; Vice President, Thelma Estrin, Ph. D., Director, Data Processing Laboratory, Brain Research Institute at UCLA, Calif.; Secretary, Paul W. Mayer, M.D., Clinical Associate Professor of Orthopaedic Surgery, University of Miami Medical School, Miami, Fla.; and Treasurer, Daniel D. Reneau, Jr., Ph. D., Professor and Head, Biomedical Engineering Department, Louisiana Tech University, Louisiana.

DIRECTORY OF SCIENTISTS WITH HANDICAPPING CONDITIONS

The Project on the Handicapped in Science of the American Association for the Advancement of Science (AAAS) is developing a directory of scientists with handicapping conditions.

Research for the publication is supported by the National Science Foundation.

Scientists listed in the directory will be asked if they would be willing to act as evaluators, consultants, or advisors on many levels concerning science and the handicapped.

NATIONWIDE SURVEY PLANNED

The Veterans Administration, Department of Medicine and Surgery, has awarded the National Amputation Foundation a con-

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tract to undertake a survey of the status and prosthetic needs of service-connected amputees.

The survey is expected to provide a representative view of the rehabilitation achieved and to identify the needs for the development of new prosthetic devices and treatment techniques.

14TH WORLD CONGRESS OF REHABILITATION INTERNATIONAL – JUNE 22-27, 1980

The Canadian Rehabilitation Council for the Disabled is hosting the 14th World Congress of Rehabilitation International in Winnipeg, Manitoba, Canada.

The purpose of the Congress is to serve the interests of all concerned with disability, prevention, and rehabilitation.

The theme of the Congress is "Prevention–Integration: Priorities for the '80's".

(For information: World Congress of Rehabilitation International, c/o Canadian Rehabilitation Council for the Disabled, P.O. Box 1980, Winnipeg, Manitoba, Canada. R3C3R3.)

SPACE SHUTTLE–1980's

Two VA physicians have been selected and will report to the Johnson Space Center in Houston for two years of training as Mission Specialists for America's Space Shuttle Corps. They are Margaret Rhea Seddon, M.D., a 3rd-year surgical resident at the VA Hospital, Memphis, Tenn., and Norman Thagard, M.D., an intern at the VA Hospital, Charleston, Va.

Dr. Seddon and Dr. Thagard are two of 35 selected from 8,079 applicants.

HENRY H. KESSLER, M.D., Ph. D., 1896-1978

Dr. Henry H. Kessler, who died on January 18, 1978, often described admiringly the tremendous resources available in his patients. In turn, his friends admired the imagination, talents, and energies he displayed over an eventful career as orthopedic surgeon and as a spokesman for rehabilitation, whose essence he defined as "ideas."

He was born in Newark, New Jersey, on April 10, 1896. With the aid of a scholarship and work as a writer and night chef, he took the premedical course at Cornell University at Ithaca, then worked his way through the Cornell Medical School in New York City. His original interest was in obstetrics, but during his internship at

Newark City Hospital he volunteered to assist part-time Dr. Fred H. Albee, a great orthopedic surgeon of World War I. Dr. Albee, first chairman of the pioneering New Jersey Rehabilitation Commission, was attempting, on a very small budget, to transfer the methods of *his successful reconstruction* hospital for war-wounded to a small state-sponsored clinic for injured workmen. It was housed in a loft of a factory building, on the floor below the Workmen's Compensation Bureau, which provided cases. Months after completing internship, Dr. Kessler was hired as full-time staff member. Eventually he became Medical Director of the Clinic and later of the New Jersey Rehabilitation Commission. Despite an attack of tuberculosis, he earned an M.A. degree at Columbia University; still later he received a Ph. D. there. He had gradually developed associations with other hospitals and a private practice and made several trips abroad by the time World War II began. After a brief period of examining recruits, he was sent to the South Pacific to treat wounded from Guadalcanal. By October, 1943, he was transferred to Mare Island, California.

Because Dr. Kessler was a Cornell graduate as well as a distinguished orthopedic surgeon and rehabilitation pioneer and because he was currently stationed at the amputation service at the Mare Island Naval Hospital with a fascinating story to tell, he was the principal speaker at the monthly meeting of the Cornell Club of San Francisco on the first Wednesday of July, 1944. A skilled raconteur, he fascinated the audience with moving tales of the rehabilitation of amputees at a variety of levels and disabilities, some of them bilaterals. He told a number of anecdotes of specific patients, both civilian before the war and the Naval and especially Marine patients whom he had seen in the South Pacific and at Mare Island. These impressed, amused, and often moved his audience of fellow Cornellians. The only slight problem was a color motion picture including some scenes of revision amputations which some of the members found a bit disturbing immediately after a delightful lunch!

Because I was a Cornell mechanical engineer, teaching at that time at the University of California at Berkeley, I attended this meeting and listened with great interest. Fortunately the motion picture did not upset me, but the numerous scenes of construction of artificial limbs, of the process of *fitting* and *alignment*, and of amputee gait appealed to my already existing interest in mechanics of the body. That area had been suggested to me by the late Professor L. M. K. Boelter in 1942 when I was assigned to teach analytical mechanics to the engineering students. After the meeting I talked with Dr. Kessler of my interest in the applications of mechanics to the human body, a field which was just beginning to be called

biomechanics. He seemed interested and suggested that we get together again to discuss the engineering problems related to artificial limbs.

Unfortunately, before I had an opportunity to visit Mare Island, Professor Howard Eberhart of the Civil Engineering faculty of Berkeley lost his leg in an accident in August, 1944. Dr. Verne T. Inman of the UC-BL Medical School, who had already been working with Professor Eberhart on analysis by engineering methods of the forces in the tendons about the shoulder joint, had to perform the below-knee amputation. As a result of seeing the Navy film and hearing Dr. Kessler's talk, I was able to reassure a number of our engineering colleagues (who had misinterpreted the shocking report, "he lost his leg," as meaning a hip disarticulation) that a below-knee amputee was capable of a very high degree of rehabilitation. I visited Professor Eberhart at the University of California Hospital, where I found him working on the problem of mechanics of the shoulder joint as a sort of occupational therapy to take his mind, as he said, off the pain in his stump. I was able to tell him of the Kessler lecture.

Through other sources entirely, Professor Eberhart was sent to Mare Island to be fitted with a temporary artificial limb of the type then being used by Dr. Kessler. It consisted of felt wrapped around the stump and encased in plaster of Paris bandage into which were incorporated brace-like side bars fastened to a wooden ankle block and the conventional single-axis ankle attached to the artificial foot.

Dr. Kessler had long been an advocate of cineplasty, particularly using skin-lined tunnels through the forearm muscles, based on his visit to Dr. Ferdinand Sauerbruch at Berlin in 1928. This technique was used rather extensively at Mare Island. In later years we saw at a National Research Council meeting one of Dr. Kessler's patients who possessed strong forces and substantial excursions, but unfortunately he was relatively rare. A great many of the patients had quite limited forces and excursion from forearm cineplasty. Among the great advantages, of course, were dexterity and sensory feedback. Some people returned to playing the piano with dramatic success, using a split hook easily adjustable in span to strike chords accurately. A natural sensory feedback resulted from muscle proprioception in the muscles normally controlling the fingers and from the pressures in the tunnels from the pegs reflecting the pressure between the fingers and thumb as long as direct control was being used. The limitation of this sensory feedback, however, was that in order to obtain strong forces, many patients necessarily used a special "advancing" lock which both closed the grip slightly further and locked the hand.

After the war Dr. Kessler not only rebuilt his private practice but was able to establish the Kessler Institute for Rehabilitation in South Orange, New Jersey. The early patients were paraplegics sent by the United Mine Workers Welfare and Retirement Fund. The Fund collected royalties from the coal companies on the coal mined. It was able to send former military ambulance railroad cars and other vehicles into the mountains of Appalachia to bring out miners who in many cases had been left neglected in local hospitals or in their homes after coal mine accidents had broken their backs; their conditions were often complicated by amputations or other disabilities.

The development of spinal cord injury care during World War II had, of course been dramatic, leading to much higher probability of survival and recovery, control and elimination of urinary infections and pressure sores, and vigorous methods for rehabilitation. Dr. Howard Rusk, after leaving the Army Air Corps and setting up what is now the Institute of Rehabilitation Medicine at New York University, and Dr. Kessler and his Institute played major roles in the transfer of these military developments to a large scale civilian application. Both Institutes played major roles in the training of large numbers of doctors, nurses, therapists, counselors, and orthotists in the special techniques involved in rehabilitation of the spinal cord, amputees, hemiplegics, and other severely disabled.

This concept of special rehabilitation institutes likewise represented a transfer to civilian life of the major rehabilitation centers which had been rapidly built up by military and naval establishments but then, like Dr. Albee's military hospital, quickly disbanded a year or two after the war ended as the military patients were released and transferred to the care of the Veterans Administration. Fortunately many reserve officers besides Drs. Kessler and Rusk retained their enthusiasm for interdisciplinary rehabilitation of the amputees, spinal-cord-injured, or blind as they returned to private practice and teaching. They have served in key roles in programs for vocational rehabilitation, crippled children, and veterans.

Dr. Kessler, whose early years had been at the Hospital for Crippled Children in Newark, N.J., was a pioneer in advocating prompt care of child amputees including congenitals. The Kessler Institute of Rehabilitation not only treated patients individually but for many years held annual child amputee conferences to which both professionals and families of child amputees were invited. These typically included demonstrations of some severely handicapped children who had been rehabilitated. Dr. Kessler had some very severely involved children as patients long before the Thalidomide disaster in Europe. He often used cineplasty or, in later years,

pneumatic externally powered arms on severely handicapped bilateral upper-limb amputees.

Large numbers of visitors to the Kessler Institute carried away both technical knowledge and inspiration. In turn, Dr. Kessler himself was a frequent traveler to many parts of the world, stimulating local programs, lecturing, and serving as an expert consultant for international organizations, foreign governments, and private charitable organizations in many countries. He was a dynamic spokesman for rehabilitation, with a fund of anecdotes and examples to illustrate the key points of his talks.

He was elected the president of the then International Society for the Welfare of Cripples in 1948, giving that organization new vitality and much greater influence. The successor organization is now known as Rehabilitation International with widespread member societies in various countries, and holds an official consultative status to the United Nations. When he attended in 1972 International Congress of Rehabilitation International at Sydney, Australia, he practically held court, with a steady stream of visitors and admirers calling upon him.

In 1954 the World Health Organization organized a conference on amputations and prostheses at Copenhagen, Denmark with a dozen participants. Dr. Kessler was unanimously elected president, with Sir Harry Platt of Great Britain, then president of the British Orthopaedic Association, as vice-president and Dr. Gudmund Harlem of Norway, later Minister of Health in Norway, as Rapporteur. I have always felt that I was both honored and fortunate in being selected to be a participant, the only non-medically trained member of the group. It was a delight to watch Dr. Kessler's skillful channeling of discussion and suave methods of reconciling differences of opinions in this very diverse international group. One evening during the conference Dr. Knud Jansen of Denmark, later chairman of the Rehabilitation International Committee on Prosthetics and Orthotics and first president of the International Society for Prosthetics and Orthotics, invited some of us, including Dr. Kessler and me, to dinner at his apartment, then at the Orthopedic Hospital. It was a charming evening and a delightful opportunity to meet informally with great people.

As an orthopedic surgeon himself, he tried to keep orthopedic surgeons interested in the field of rehabilitation at a time when many were so busy with new operating techniques that they tended to lose interest in the welfare of the patients after the scar had healed. Dr. Kessler presented or discussed papers at the American Academy of Orthopaedic Surgeons and his exhibit on cineplasty in 1936 won the gold medal.

When the American Board for Certification in Orthotics and Prosthetics was organized in 1948 by farsighted leaders of the prosthetics and orthotics industry, they decided to take the highly unusual step of inviting members of another profession to participate on the Board of Directors. Four of the seven directors were selected from among the leading prosthetists and orthotists, but three were nominated by the American Academy of Orthopaedic Surgeons. Dr. Kessler was, as I recall, among the first three selected to serve on this very important Board to certify both individual practitioners and the facilities in which they practice. Dr. Kessler's early service on this Board undoubtedly helped to establish confidence and respect for its efforts. His genial methods of reconciling differences helped develop mutual respect among the members and the middle-aged or older individuals undergoing the certification process.

A major dinner in his honor was held at the Waldorf Astoria Hotel in New York City on the occasion of his 70th birthday attended by a large ballroom full of admirers and enthusiastic supporters. It was only one of many tributes paid to him.

His autobiography, *The Knife Is Not Enough*, published by W. W. Norton in 1968, presented a fascinating story of his own early struggles for education, for rehabilitation in general, and for treatment of amputation and spinal cord injury in particular. It is replete with anecdotes and moving stories of some of his cases as well as numerous details of his own life, adventures in many nations, honors, and occasional disappointments. An earlier book, *Peter Stuyvesant and His New York*, Random House, 1959, described his research establishing that the colonial governor of New Amsterdam had lost his right leg.

In the passing of this pioneer, the world has lost a kindly and gentle man. The fields of rehabilitation as a whole and especially after amputation or spinal cord injury, particularly the orthopedic aspects, have lost a champion.

Eugene F. Murphy

HENRY H. KESSLER MEMORIAL FELLOWSHIP

Howard A. Rusk, M.D., president of the World Rehabilitation Fund has announced the creation of the Henry H. Kessler Memorial Fellowship in honor of the world-renowned authority on rehabilitation.

A physician from Bandung, Indonesia, has received the first fellowship for advanced training in rehabilitation medicine at the Santo Tomas University Hospital in the Philippines.

RECENT PATENTS[a]

Alignment Device for Artificial Limbs. Denis R. W. May, assignor to J. E. Hanger and Co., London, England. Clamping screws on the alignment device may be loosened or the device dismantled without the loss of a desired alignment setting. (Patent No. 3,982,278, Sept. 28, 1976; filed Jan. 29, 1976, Appl. No. 653,605; 5 claims.)

Bioelectrodes. Takuya R. Sato. This bioelectrode design features a pad of electrolyte-filled absorbent material arranged to press against the skin at all times, thus ensuring good electrical contact. (Patent No. 3,982,529, Sept. 28, 1976; filed Aug. 7, 1975, Appl. No. 602,611; 41 claims.)

Fluid-Filled Cushioning Assemblies: J. Herbert Keeton. A compartmented cushion is filled with fluid. The individual cells may either be sealed off or a free exchange of fluid may be produced by opening valves between cells. It is claimed that by control over flow, the cushion shape may be varied as desired. (Patent No. 3,984,886, Oct. 12, 1976; filed Aug. 20, 1975, Appl. No. 606,079; 5 claims.)

Functional Ankle for a Prosthetic Limb: Charles C. Asbelle, Gene R. Helmuth, William R. Applegate, and Gerald K. Porter, assignors to the Secretary of the Navy, Washington, D.C. An improvement of the SACH foot in which an additional block of rubber is so mounted as to permit transverse rotation. (Patent No. 3,982,280, Sept. 28, 1976; filed Oct. 6, 1975, Appl. No. 619,873; 1 claim.)

Inflation Device for a Pneumatic Orthosis: Donald K. Shaffer, assignor to Thiokol Corp. Pneumatic orthoses are usually inflated with an electric motor driven compressor. This invention would employ gas cartridges, carried in two canes, to achieve the necessary inflation. So equipped, the user can inflate the orthosis without access to external power. (Patent No. 3,982,531, Sept. 28, 1976; filed April 30, 1975, Appl. No. 572,980; 14 claims.)

Mechanical Prosthesis of the Knee: Mario C. Valenti and Jorge C. Samaranch. A weight-operated mechanical knee brake, claimed to offer superior stability on ramps. (Patent No. 3,982,279, Sept. 28, 1976; filed March 6, 1975, Appl. No. 556,112; 5 claims.)

Method of and Means For Scrambling and Descrambling Speech at Audio Frequencies: Daniel Graupe, Fort Collins, Colo. and G. Donald Causey, Chevy Chase, Md., assignors to Biosystems Research Group II, Chevy Chase, Md. A method for processing an input audio-frequency signal which is to be transmitted through a communication channel, comprising scrambling the input signal, transmitting the analog signal through the channel, and descrambling the transmitted scrambled analog signal. (Patent No. 4,086,435, filed Sept. 17, 1976, Appl. No. 724, 170, 18 claims.)

Photocurable Contour Conforming Splint: Donald C. Garwood and Harry Taw, assignors to Merck and Co., Inc. A splint material of fabric impregnated by a photocurable resin,

[a]Patents may be ordered by number from the Commissioner of Patents, Washington, D.C., 20231, at 50¢ each.

after molding, is cured by exposure to a bank of powerful fluorescent lamps. It is claimed that the resulting matrix is air and water permeable and rigid even when wet. (Patent No. 3,985,128, Oct. 12, 1976; filed June 2, 1975, Appl. No. 583,122; 12 claims.)

Vehicle Invalid Lift Device: Otto C. Holecek. Mounted to a car door frame, an apparatus capable of transferring an invalid into or out of a car seat may be either mechanically or hydraulically powered. It is not necessary to drill holes in the car frame; the device may be quickly mounted and removed. (Patent No. 3,983,584, Oct. 5, 1976; filed June 17, 1975, Appl. No. 587,555; 13 claims.)

Wheel or Geriatrics Chair Cushion: Jody A. Gorran. Compartments of air and fluids within the cushion provide a soft and stable base for the patient. It is claimed that the stabilizing features are particularly important to feeble subjects. An overflow chamber accepts any leak. (Patent No. 3,983,587, Oct. 5, 1976; filed Sept. 23, 1975, Appl. No. 616,045; 12 claims.)

Wheelchairs: Robert B. Bonfield, assignor to Bardic Engineering Limited, Southampton, England. A hydraulic wheelchair attachment acts to raise the back end of a wheelchair, thus permitting easier entrance and exit. Manually operated pumps and selector valves are incorporated. (Patent No. 3,985,389, Oct. 12, 1976; filed June 23, 1975, Appl. No. 589,791; 21 claims.)

PUBLICATIONS OF INTEREST

PROSTHETICS

Amputations Resulting from Electrical Injury: A Review of 22 Cases, Thomas C. LaBorde and Robert H. Meier, III; Arch. Phys. Med. and Rehab., 59(3):134-137, Mar. 1978.

Comparison of Codes for Sensory Feedback Using Electrocutaneous Tracking, Andrew Y. J. Szeto and John Lyman; Ann. Biomed. Engng., 5:367-383, 1977.

"Floating-Socket" Total Shoulder Replacement: Anatomical, Biomechanical, and Surgical Rationale, Frederick F. Buechel, Michael J. Pappas, and Anthony F. DePalma; J. Biomed. Mat. Res., 12:89-114, 1978.

Functional Capabilities of Lower Extremity Amputees, Bernice Kegel, Margaret L. Carpenter, and Ernest M. Burgess; Arch. Phys. Med. & Rehab., 59(3):109-120, Mar. 1978.

The Knud Jansen Lecture—Above-Knee Prosthetics, C. W. Radcliffe; J. International Soc. Prosth. & Ortho., 1(3):146-160, Dec. 1977.

Limb Prosthetics and Orthotics, Report of a Workshop, University of Miami, April 1-3, 1977; Ortho. & Prosth., 31(4):1-73, Dec. 1977.

A Modification of the Porous Below-Knee Soft Socket Insert, Arthur Scheinhaus, and Gustav Rubin; Ortho. & Prosth.; 32(1):3-5, Mar. 1978.

New Dimensions for Prosthetic Socks, Martha Field; Ortho. & Prosth., 32(1):10-15, Mar. 1978.

A Quick-Change Ankle Disconnect for a Below-Knee Amputation, Ernest Baehr and John Simek; Ortho. & Prosth., 32(1):32-35, Mar. 1978.

Videotape Immediate Playback: A Tool in Rehabilitation of Persons with Amputations, Justin Alexander and Ronald Goodrich; Arch. Phys. Med. and Rehab., 59(3):141-143, Mar. 1978.

ORTHOTICS

The Cast-Brace Treatment of Femoral Shaft Fractures, D. Wardlaw; J. Bone & Joint Surg. (British Vol.), 59-B(4):411-417, Nov. 1977.

Clinical Assessment of a New Weight-Relieving Brace, E. G. Anderson, P. L. Frank, J. T. Henshaw, and H. G. Rae; J. Bone & Joint Surg. (British Vol.), 59-B(4):439-446, Nov. 1977.

The Foot and Footwear, P. K. Sethi; J. International Soc. Prosth. & Ortho.; 1(3):173, 182, Dec. 1977.

The Iowa Knee Orthosis, Donald Shurr, Harold Miller, John Albright, and Harley Feldick; Ortho. & Prosth., 32(1):20–24, Mar. 1978.

Limb Prosthetics and Orthotics, Report of a Workshop, University of Miami, April 1–8, 1977, Ortho. & Prosth., 31(4):1–78, Dec. 1977.

A New Non-Invasive Halo Orthosis for Immobilization of the Cervical Spine, C. L. Wilson, A. G. Hadjipavlon, and G. Berretta; Ortho. & Prosth., 32(1):16–19, Mar. 1978.

Plastics in Lower-Limb Orthotics, Warren A. Carlow, and Manuel J. Almeida; Ortho. & Prosth., 32(1):25–31, Mar. 1978.

SURGERY

Complications of Trochanteric Osteotomy in Total Hip Replacement, Harlan C. Amstutz, and Sinan Maki; J. Bone & Joint Surg., 60-A(2):214–217, Mar. 1978.

Dislocations after Total Hip-Replacement Arthroplasties, George E. Lewinnek, Jack L. Lewis, Richard Tarr, Clinton L. Compere, and Jerald R. Zimmerman; J. Bone & Joint Surg., 60-A(2):217–221, Mar. 1978.

Posterior Spine Stabilization with Methylmethacrylate, Biomechanical Testing of a Surgical Specimen, Manohar M. Panjabi, William Hopper, Augustus A. White, III, and Kristaps J. Keggi; Spine, 2(4):241–247, Dec. 1977.

Reattachment of the Greater Trochanter in Total Hip-Replacement Arthroplasty—A New Technique, William H. Harris, and Omar D. Crothers; J. Bone & Joint Surg., 60-A(2): 211–214, Mar. 1978.

Surgical Treatment of Pressure Ulcers, Stephen J. Herceg and Robert L. Harding; Arch. Phys. Med. Rehab., (59):198–200, April 1978.

Total Hip Replacement with and without Osteotomy of the Greater Trochanter—Clinical and Biomechanical Comparisons in the Same Patients, H. James Wiesman, Jr., Sheldon R. Simon, Frederick C. Ewald, William H. Thomas, and Clement B. Sledge; J. Bone & Joint Surg., 60-A(2):208–211, Mar. 1978.

Wound Healing After Amputation: Effect of Controlled Environment Treatment—A Preliminary Study, Ernest M. Burgess; J. Bone & Joint Surg., 60-A(2):245–247, Mar. 1978.

SENSORY AIDS

A Comparison of Hearing Aids with Amplitude Compression, Igor V. Nabelek and Larry N. Robinette; Audiol., 16:78–85, 1977.

Environmental Modifications for the Visually Impaired: A Handbook, John Duncan, Calasha Gish, Mary Ellen Mulholland, and Alex Townsend; J. Vis. Impair. & Blindness, 71(10):441–455, Dec. 1977.

Interagency Cooperation in an Adult Discussion Group for Visually Impaired Older People, Donna L. Emerson and Marla Long; J. Vis. Impair. and Blindness, 72(1):15-19, Jan. 1978.

A Nonlinear Receptive Field Model of the Visual System, Tomozo Furukawa and Shiro Hagiwara; IEEE Trans. Biomed. Engng., BME-25(1):76-83, Jan. 1978.

The Relative Importance of Recovery Time in Compression Hearing Aids, H. C. Schweitzer and G. D. Causey; Audiol., 16:61-72, 1977.

The Use of Myoelectric Feedback in Teaching Facial Expression to the Blind, Colleen Webb; Biofeedback and Self-Regulation, 2(2):147-160, 1977.

GENERAL

Amputation Surgery in the Lower Extremity—Part II, G. Murdoch; J. International Soc. Prosth. & Orth., 1(3):183-192, Dec. 1977.

The Basic Kinematics of the Human Spine, A Review of Past and Current Knowledge, Augustus A. White, III and Manohar M. Panjabi; Spine, 3(1):12-20, Mar. 1978.

Broadband Pulsed Doppler Ultrasonic System for the Noninvasive Measurement of Blood Velocity in Large Vessels, F. J. Thompson; Med. & Biol. Engng. & Comput., 16:135-146, Mar. 1978.

Cane *Technique: Modifying the Touch Technique for Full Path* Coverage, Mark M. Uslan; J. Vis. Impair & Blindness, 72(1):10-14, Jan. 1978.

Comparison of a Dynamic and Steady-State Model for Determining Nerve Fiber Threshold, David A. Teicher and Donald R. McNeal; IEEE Trans. Biomed. Engng., BME-25(1): 105-107, Jan. 1978.

Dual-Channel Audio Monitor for Distinguising Action Potentials from Two Different Sources, Andrew D. McClellan and Christopher S. Cohan; Med. & Biol. Engng. & Comput., 16:203-206, Mar. 1978.

Energy Cost of Ambulation in Health and Disability: A Literature Review, Steven V. Fisher and Glenn Gullickson, Jr.; Arch. Phys. Med. & Rehab., 59(3):124-133, Mar. 1978.

Factors Influencing Manual Muscle Tests in Physical Therapy—The Magnitude and Duration of Force Applied, *James A. Nicholas, Alexander Sapega, Harry Kraus, and Joseph N.* Webb; J. Bone & Joint Surg., 60-A(2):186-191, Mar. 1978.

Graphical Analysis of Forces Acting Upon a Simplified Model of the Foot, G. Veres; J. International Soc. Prosth. & Orth., 1(3):161-172, Dec. 1977.

Hand Controls and Assistive Devices for the Physically Disabled, Menahem Less, Edward C. Colverd, John J. Dillon, Judy Young; Human Resources Center, Albertson, N.Y. 11507, 1977.

An Instrument to Measure Cutaneous Blood Flow Using the Doppler Shift of Laser Light, Dennis Watkins and G. Allen Holloway, Jr.; IEEE Trans. Biomed. Engng., BME-25(1): 28-34, Jan. 1978.

Kinesiology of the Transplanted Muscle, M. Mussen; Electromyogr. Clin. Neurophysiol., 17:455-467, 1977.

A Manually-Operated Portable Stairclimbing Wheelchair, Maurice N. Brearley; J. Bioengng., 1:413-418, Sept. 1977.

Modifications of a MacLaren Buggy Major for Orthopaedic Seat Inserts, Edward L. Barber; Ortho. & Prosth., 32(1):6-9, Mar. 1978.

On a Three-Link Model of the Dynamics of Standing Up and Sitting Down, H. Hemami and Vijay C. Jaswa; IEEE Trans. Systems, Man, & Cybernetics, SMC-8(2):115-121, Feb. 1978.

Orthostatic Hypotension in Amputees and Subjects with Spinal Cord Injuries, Y. Shoenfeld, Y. Shapiro, A. Ohry, Y. Levy, R. Udassin, Y. Drory, R. Rozin, and E. Sohar; Arch. Phys. Med. & Rehab., 59(3):138-140, Mar. 1978.

Psychological Considerations in the Adjustment to Spinal Cord Injury, Thomas D. Stewart, and Alain B. Rossier; Rehab. Lit., 39(3):75-80, Mar. 1978.

Rehabilitation Outcome of Patients with Dual Disability of Hemiplegia and Amputation, George Varghese, Catherine Hinterbuchner, Philip Mondall, and Joji Sakuma; Arch. Phys. Med. & Rehab., 59(3):121-123, Mar. 1978.

Sexual Adjustment of Spinal Cord Injured Veterans Living in the Community, Anne H. Berkman, Rae Weissman, and Maxwell H. Frielich; Arch. Phys. Med. & Rehab., 59:29-33, Jan. 1978.

Three-Dimensional Work Space of the Amputee, Carolyn K. Rozier; Human Factors, 19(6):525-533, 1977.

Ultrastructural Changes of the Back Muscles of Idiopathic Scoliosis, Y. C. Wong, A. C. M. C. Yau, W. D. Low, and F. P. Lisowski; Spine, 2(4):251-259, Dec. 1977.

Wheelchair Cushion Effect on Skin Temperature, Steven V. Fisher, Thomas E. Szymke, Sunanda Y. Apte, and Michael Kosiak; Arch. Phys. Med. & Rehab., 59:68-72, Feb. 1978.

CALENDAR OF EVENTS

3rd Conference on Materials for Use in Medicine and Biology, Mechanical Properties of Biomaterials, Keele University, Keele, Staffordshire, U.K. Sept. 13-15, 1978. **Bioceramics Symposium** Sept. 16. (For information: Dr. G. W. Hastings, Bio-Medical Engineering Unit, c/o Medical Institute, Hartshill, Stoke-on-Trent, Staffordshire ST4 7NY, England.)

National Rehabilitation Association, 1978 National Conference, the Salt Palace, Salt Lake City, Utah, Sept. 23-27, 1978.

31st Annual Conference on Engineering in Medicine and Biology (ACEMB), Marriott Hotel, Atlanta, Georgia, Oct. 21-25, 1978. (For information: Patricia I. Horner, Suite 404, 4405 East-West Highway, Bethesda, Maryland 20014; tel. 301-657-4142.)

American Society of Biomechanics, Second Annual Meeting, University of Michigan, Ann Arbor, Michigan, Oct. 26-27, 1978. (For information: Albert Schultz, Materials Engineering, University of Illinois at Chicago, Box 4348, Chicago, Ill. 60680.)

American Academy of Physical Medicine and Rehabilitation and American Congress of Rehabilitation Medicine Convention, New Orleans, La., Oct. 29-Nov. 3, 1978.

Optical Society of America (OSA), Annual Meeting, Jack Tar Hotel, San Francisco, Calif., Oct. 30-Nov. 3, 1978. (For information: W. J. Quinn, Optical Society of America, Suite 620, 2000 L St., N.W., Washington, D.C. 20036.)

American Orthotic and Prosthetic Association (AOPA), National Assembly, Town & Country Hotel, San Diego, Calif., Oct. 31-Nov. 4, 1978.

American Speech and Hearing Association (ASHA), San Francisco, Calif., Nov. 18-21, 1978.

Acoustical Society of America, Honolulu, Hawaii, Nov. 26-Dec. 1, 1978.

American Society of Mechanical Engineers (ASME) Winter Annual Meeting, San Francisco, Calif., Dec. 10-15, 1978.

5th Asian Conference on Work for the Blind, Hong Kong, Dec. 1978. (For information: World Council for the Welfare of the Blind, 58 Avenue Bosquet, Paris 75007, France.)

International Association for Prevention of Blindness Conference, Kyoto, Japan, 1978. (For information: Dr. W. J. Holmes, 1013 Bishop St., Honolulu, Hawaii 96813.)

Rehabilitation International Medical Commission, 4th International Seminar, Southampton, United Kingdom, 1978. (For information: Prof. Dr. Karlheinz Renker, Gesellshaft fur Rehabilitation in der DDR, Harz 42-44 Halle (Saale), German Democratic Republic.)

American Academy of Orthopaedic Surgeons (AAOS), Annual Meeting, Brooks Hall Convention Center, San Francisco, Calif., Feb. 22-27, 1979.

American Occupational Therapy Association, Annual Conference, Plaza Hotel, Detroit, Michigan, April 22–27, 1979. (For information: Monty Hicks at (301) 770-2200.)

6th Pan-Pacific Conference on Rehabilitation, Seoul, Republic of Korea, April 22-27, 1979. (For information: Pyung K. Moon, M.D., President, Korean Society for Rehabilitation of the Disabled, 15-San, Sinchong-dong, Sudaemoon-ku, Seoul, Korea.)

11th International Biomaterials Symposium in Conjunction with the 5th Annual Meeting of the Society of Biomaterials, Clemson University, Clemson, South Carolina 29631, April 28-May 1, 1979.

Biomechanics Symposium in connection with the ASME 1979 Summer Applied Mechanics/Bioengineering/Fluids Engineering Conference (co-sponsored by the Canadian Society for Mechanical Engineering). Niagara Falls, New York, June 18–20, 1979. (For information: Albert B. Schultz, University of Illinois at Chicago, Department of Materials Engineering, Box 4348, Chicago, Illinois 60680.)

8th Congress of the World Federation of the Deaf, Varna, Bulgaria, June 20-26, 1979. (For information: Secretariat General, Union of the Deaf of Bulgaria, 3 Bd Ul Zaimov, Sofia, Bulgaria.)

American Physical Therapy Association, Annual Conference, Atlanta, Georgia, June 25–29, 1979.

5th World Conference on the Theory of Machines and Mechanisms, Montreal, Canada, July 8–13, 1979. (Canadian Council of the International Federation of Theory of Machines and Mechanisms, in cooperation with the *USCTOMM.*)

6th World Assembly of the World Council for the Welfare of the Blind, Kaduna, Nigeria, Oct. 8–12, 1979. (For information: WCWB, 58 Avenue Bosquet, Paris 75007, France.)

Optical Society of America (OSA), Annual Meeting, Holiday Inn/Americana Flagship Hotel, Rochester, New York, Oct. 7–12, 1979.

American Orthotic and Prosthetic Association (AOPA), National Assembly, Washington, D.C., Oct. 23–27, 1979.

American Academy of Physical Medicine and Rehabilitation and American Congress of Rehabilitation Medicine Convention, Honolulu, Hawaii, Nov. 11–16, 1979.

American Speech and Hearing Association (ASHA), Annual Meeting, Atlanta, Georgia, Nov. 15–18, 1979.

American Society of Mechanical Engineers (ASME), Winter Meeting, New York, N.Y., Nov. 25-30, 1979.

Acoustical Society of America, Salt Lake City, Utah, Nov. 26–30, 1979.

3rd International Congress on "Improving the Quality of Life of the Handicapped with Assistive Devices," U.S.A., Nov. 1979. (For information: World Veterans Federation, 16 Rue Hamelin, Paris, France.)

2nd International Symposium for Facial Prostheses, England, 1979. (Note: this is the tentative re-scheduling of a meeting announced for May 4-6, 1978, and cancelled.)

American Corrective Therapy Association, Annual Meeting, Portland, Oregon, 1979. (For information: Dept. of Corrective Therapy, Dr. Oral Mathison, Chief, VA Hospital, Battle Creek, Michigan, tel. (616) 372-3281.)

Latin American Association for Rehabilitation Medicine (AMLAR) Guatemala, 1979.

American Occupational Therapy Association, Annual Meeting, Denver, Colorado, 1979.

American Academy of Orthopaedic Surgeons (AAOS), Atlanta, Georgia, Feb. 7-12, 1980.

World Biomaterials Congress, Baden/Vienna, Austria, April 8-12, 1980. (For information: Society for Biomaterials, 6220 Culebra Road, San Antonio, Texas 78284.)

8th International Congress of the International Federation of Physical Medicine and Rehabilitation, Stockholm, Sweden, May 1980. (For information: International Federation of Physical Medicine and Rehabilitation, Zonhove 70 Nieuwstraat, Son, the Netherlands.)

14th World Congress of Rehabilitation International, Winnipeg Convention Centre, Winnipeg, Canada, June 22-27, 1980. (For information: 14th World Congress of Rehabilitation International c/o Canadian Rehabilitation Council for the Disabled, Box 1980, Winnipeg, Manitoba, Canada R3C 3R3.)

American Speech and Hearing Association (ASHA), New Orleans, La., Nov. 5-9, 1980.

International Society for Prosthetics and Orthotics (ISPO), the Netherlands, 1980.

4th World Congress of the International Rehabilitation Medicine Association, Stockholm, Sweden, 1980. (For information: International Rehabilitation Medicine Association, CH-7310 Bad Ragaz, Switzerland.)

(Tentative) **American Orthotic and Prosthetic Association (AOPA),** National Assembly, Toronto, Ontario, Canada, 1980.

INDEX TO THE BULLETIN OF PROSTHETICS RESEARCH
BPR 10-27 and 10-28

NOTICE TO CONTRIBUTORS

We welcome contributions to the Bulletin. To facilitate publishing please:

1. Type in double space the text, figure captions, footnotes, references, and tables on one side of letter-size, plain bond paper.

2. Leave margins of 1½ inches on the left and 1¼ inches on the right.

3. Capitalize title of paper and center. Below title, center author's name(s) with highest degree or certification. Then center position title, organization, and location (full address and zip code).

4. Number pages consecutively in the lower right-hand corner of the page in pencil. Each page must start with a new paragraph. Type preceding page short if necessary. Indent paragraphs.

5. Cite all references by number in the text and list numerically at end of paper.

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Acknowledgment of all manuscripts will be made as promptly as possible.

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